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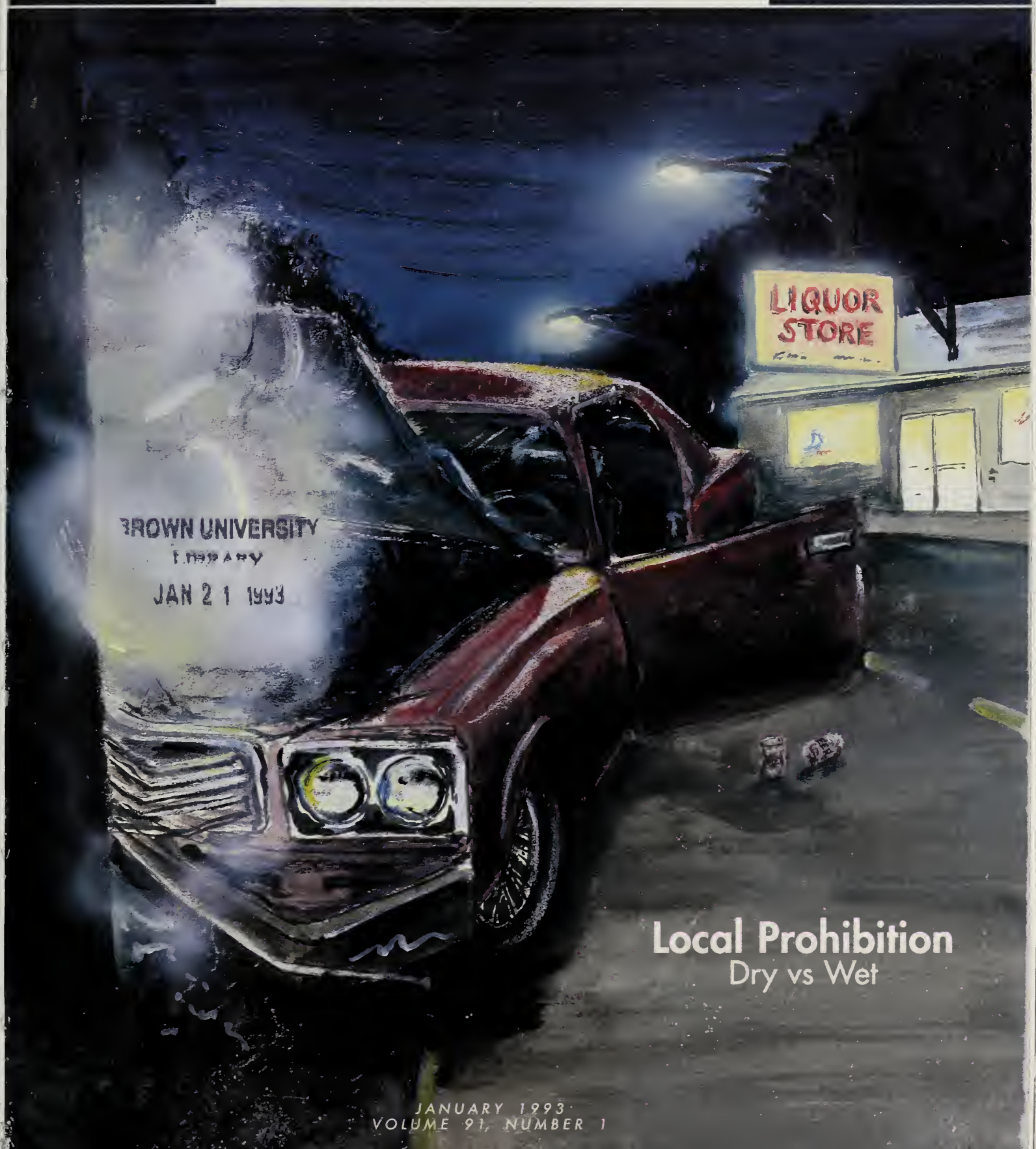
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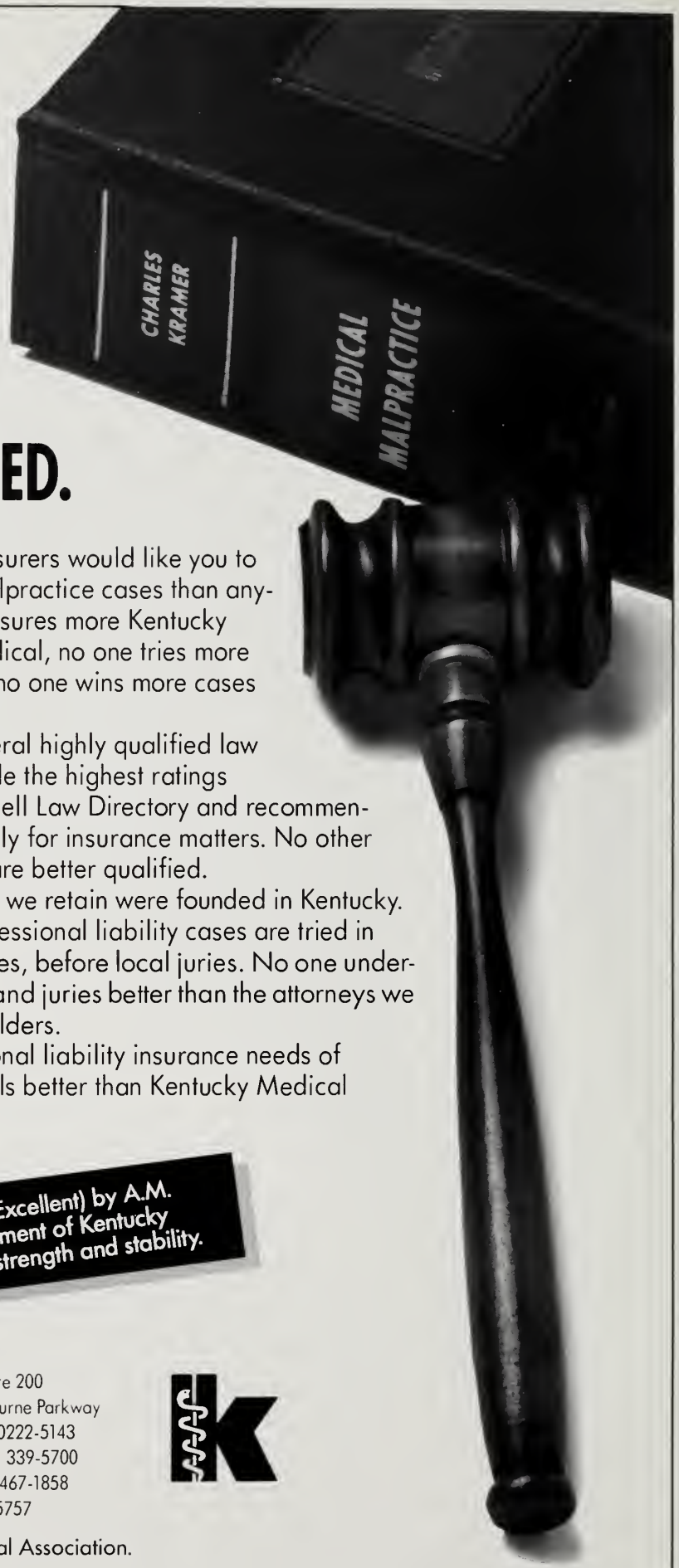


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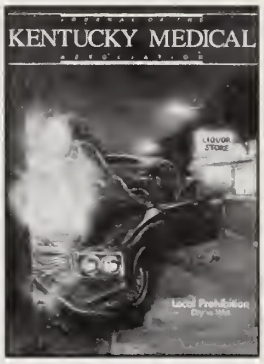
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William B. Monnig, MD

Membership in Organized Medicine:

A Privilege, A Right, A Responsibility, and An Obligation

"There is a recognized awareness that not all physicians belong to organized medicine at any level — local, state, or national — but that organized medicine is still the best, most democratically-organized, representative body to understand and advocate physician concerns and positions."

I have been President of the KMA for more than 90 days and "the honeymoon is over." As I began writing this article, the Interim Meeting of the AMA was drawing to a close in Nashville. The topic of discussion was Health Care Reform and all of its ramifications. The KMA delegation listened, learned, debated, and helped form consensus with AMA representatives from across the country about changing the health care system to meet the needs of our people for an affordable health care system that is accessible to all.

There was consensus that organized medicine should participate in formulating a national policy on health care issues and it was recognized that organized medicine should assume the role of representing the physician's interests in all forums that will be used to debate the issues. There is a recognized awareness that not all physicians belong to organized medicine at any level — local, state, or national — but that organized medicine is still the best, most democratically-organized, representative body to understand and advocate physician concerns and positions.

The national debate echoed the debate at the KMA House of Delegates and came to the same conclusion. The regional medical societies, the KMA, and the AMA will assume the mantle of authority to speak for physicians in their respective areas of governance. The elected leaders of these professional associations will remain the spokespersons for physicians but they will also assume the added responsibility for negotiating with all third parties who will help formulate the changes in the healthcare and healthcare insurance systems.

If we assume that organized medicine will be successful in assuming that mantle of authority, there is a tremendous incentive for every physician to participate as a member in each level of organized medicine. Active participation is the best way to guarantee that your voice will be heard and that your concerns will be addressed. The representative nature of organized medicine

associations permits and encourages grass roots input into policy and election of leaders. If organized medicine's policies are deemed to be inappropriate or not reflective of individual physician's concerns and positions, the policies can be altered through the House of Delegates. If the elected leaders do not perform their duties to the satisfaction of the individual physicians, the physicians can annually remove those leaders and replace them with leaders that more appropriately reflect the wishes of the individual doctors.

As I said earlier, "The honeymoon is over." I have received a few letters from good physicians who are frustrated with the KMA or the AMA. Their needs are not being met. On each occasion, we try to address their concerns, but readily admit that we do not satisfy everyone all of the time.

I am very concerned when physicians resolve their frustration by dropping their associational membership. This is not a satisfactory solution. Every time we lose a member or fail to attract a new physician to the KMA, or AMA, we further weaken the association's ability to confront or engage the outside forces who wish to influence patient care.

There is the occasional comment that the KMA or AMA is not relevant to physicians' present concerns. I can assure you that nothing is further from the truth. Whether you want to discuss health care reform, patient rights, provider taxes, professional licensing, mid-level practitioners, CLIA requirements, OSHA regulations, drug costs, etc, the KMA and the AMA are responding. We not only have policies, but are actively interacting with the agents of other interests to make certain the physician and patient viewpoints are being addressed.

"To adequately address the issues of maintaining the profession and of responding to the era of change, each physician must maintain membership in organized medicine."

Physicians frequently voice concern about the cost of associational membership. We are aware of the need to use fiscal restraint, and again each physician has the opportunity within the association to question our expenditures and modify leadership's decisions. But everyone must realize that operating the association requires revenue.

There is no organized body that does a better job of espousing its constituents' concerns for less money than does the KMA and AMA. Dues in these organizations is money well spent and paying the required dues by every physician is important to the overall successful operation of the KMA and AMA. Paying dues to support the county medical society, the KMA, and the AMA should be considered a cost of practicing the medical profession in every physician's community in the Commonwealth of Kentucky. As an example of the financial benefits of organized medicine's efforts, HCFA changed the "Physician Behavioral Offset" provisions that placed almost 10 billion dollars back in the Medicare budget. That action alone more than paid for everyone's AMA and KMA dues.

KMA and AMA membership is a privilege. Only physicians may be members. Membership is a right of every physician who is in good standing and has a valid Kentucky license. But, moreover, membership in the KMA and AMA is a responsibility. To adequately address the issues of maintaining the profession and of responding to the era of change, each physician must maintain membership in organized medicine. And, finally, membership in the regional medical society, the KMA, and the AMA carries with it the obligation to actively participate in the respective association.

The KMA leadership stands ready to assist you in any way possible to strengthen the profession through increasing membership so that all physicians will be members of our regional medical society, the KMA, and the AMA.

William B. Monnig, MD
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Prohibition Revisited: County Alcohol Control Consequences

Richard W. Wilson, DHSc, MPH; George Niva, MS; Thomas Nicholson, PhD, MPH

This study examined measures of alcohol abuse consequences in wet vs dry counties in Kentucky. Data were gathered from all counties of the state for the year 1988. Dry counties had less alcohol-related auto accidents and DUI arrests. Other alcohol-related variables, such as cirrhosis mortality, were not significantly different between wet and dry counties. When demographic variables were also considered, it was determined that the advantage enjoyed by dry counties remained. Findings indicate that county-level alcohol prohibition is effective in promoting the public's health, by improving highway safety.

Introduction

Since the repeal of the Eighteenth Amendment it has become conventional wisdom that prohibition does not work. The facts make the point debatable.[1,2] However, since national prohibition was overturned, many states have permitted local communities to decide by referendum whether alcohol sale would be permitted.

Currently, about 406 counties in 15 states exercise this "local option," prohibiting the sale of alcoholic beverages.[3] About eight million persons live in these "dry" counties. In proportion to the total US population, this is relatively few. However, at least as many others, living in neighboring counties, are indirectly effected because of the alcohol-related transportation and commerce that takes place between "dry" and "wet" counties.

Inappropriate alcohol consumption has many undesirable consequences, including highway crashes, medical problems, and crime. This study sought to determine whether county level alcohol prohibition would effectively diminish these effects of alcohol abuse.

Literature Review

While there is often debate on local prohibition within states, the lion's share of discussion is guided by attitudes, values, and beliefs, not data. However, there has been research concerning the consequences of local prohibition.

Colon did an analysis of traffic fatalities as influenced by local prohibition.[4] He compared rates of death per 1,000 licensed drivers and deaths per 10 million vehicle miles driven, as found in states with dry counties versus states with only wet counties. He further delineated single vehicle traffic fatalities and all highway fatalities. On all counts, states with dry counties had significantly higher rates of highway death. The study was limited in not controlling for other variables such as highway conditions, and it was unable to pinpoint cause. Nevertheless, it is not supportive of the efficacy of local prohibition.

In another project completed by Colon,[5] it was determined that cirrhosis mortality rates were significantly and positively correlated to on-premise availability of alcohol for all males and white females. There was no correlation between cirrhosis mortality rates and retail availability. Availability was measured by considering the implementation of nine different alcohol control measures, including local prohibition.

Hoadley et al[6] analyzed the impact of regulation and control measures, including local prohibition, over the years 1955-1980. The dependent variable was per capita consumption of distilled spirits in the 48 contiguous states. Local prohibition was an effective but modest deterrent to alcohol drinking. They also concluded that other control measures were more effective and socially more viable.

These three studies are limited in that they compare states with dry counties with those with

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none. However, states with dry counties are not totally dry. Kentucky, for example, has 120 counties, 77 of which are dry. Only half of Kentucky's population lives in dry counties. The gross comparisons done by the studies cited above would tend to underestimate the consequences of county level prohibition.

Another study specifically examined data from Kentucky. The State Department of Education completed a statewide student drug and alcohol use survey. Students were then sorted by residence in wet or dry counties and compared on their self-reported alcohol consumption. Analysis found that "moderate" drinking by teens was slightly more common in wet counties, but heavier drinking was just as prevalent in dry versus wet counties.[7]

Data Analysis

Kentucky has 120 counties. Of these, 77 are dry while 43 are wet. Two of the wet counties were removed from the analysis because they are major urban centers (Louisville in Jefferson County, and Lexington in Fayette County) while the rest of the state is predominantly rural.

County groups were then compared on the following variables: total alcohol-related highway accidents; alcohol related highway accidents with fatalities; alcohol-related highway accidents with injuries; persons killed in alcohol-related highway accidents; persons injured in alcohol related highway accidents; DUI (driving under the influence of alcohol) arrests, and juvenile (under 18) DUI arrests; murder; rape; assault; homicide; cirrhosis deaths; suicide deaths; and deaths due to congenital anomalies.

Data on highway accidents and crime were obtained from the Kentucky State Police.[8] Suicide, cirrhosis, and congenital anomaly statistics were obtained from the Kentucky Cabinet for Human Resources.[9] Demographic characteristics were obtained from the Census Bureau.[10]

Data were obtained as simple counts for each county, for the year 1988. To convert the variables into rates, county populations were obtained from the Census Bureau.[10] All rates were calculated per 100,000 population. Wet and dry counties were then formed into two groups.

It was recognized that wet and dry counties could be different in other ways besides alcohol control status. These differences could influence highway safety and other consequences of alcohol abuse. The following data were thus obtained from the Census Bureau:[10] mean county population; population per square mile; mean persons per household; percent of households headed by females; percent of adults graduated from high school; percent of adults graduated from college; crime rate; per capita income; median household income; and percent of residents in poverty. Analysis was done with the Analysis of Variance and Analysis of Covariance statistical techniques.

Results

The group of wet counties were first compared with the dry counties on the basis of all of the dependent variables. It was found that wet counties had higher rates for most variables. However, analysis of variance demonstrated a statistically significant difference between groups on only two variables: total alcohol-rated accidents and DUI Arrests. Data are presented in Table 1.

The next step in the analysis was a comparison of the county groups on the basis of the demographic covariates identified above. For every variable, there was a statistically significant difference between wet and dry counties. Data are found in Table 2. Wet counties were more population dense, were more educated, had more crime in general, and were more affluent. Because those variables could have a significant impact on alcohol consumption and the consequences of alcohol abuse, it was determined that they must be considered in data analysis.

Consequently, the final step in the analysis

Table 1. Measures of Selected Undesirable Consequences of Alcohol Abuse in Wet vs Dry Kentucky Counties, 1988. (rates/100,000)

	Wet	Dry	F
Total alcohal related highway accidents	237.6	169.4	27.88**
Alcohal related highway accidents with fatalities	13.0	10.9	1.07
Alcohal related highway accidents with injuries	110.8	98.9	1.10
Persons killed in alcahal related highway accidents	20.8	12.7	1.99
Persons injured in alcahol related highway accidents	182.5	158.2	2.10
DUI arrests	1253.6	930.3	17.02**
Juvenile DUI arrests	31.9	31.3	0.02
Murder	4.56	8.52	1.21
Rape	19.53	30.25	0.16
Assault	220.83	124.06	9.97
Hamicide deaths	5.45	5.56	0.00
Cirrhosis deaths	7.37	7.66	0.04
Suicide deaths	13.1	12.44	1.32
Cangenital anomalies	6.58	4.88	2.46

*Significant at $p < 0.025$; ANOVA
**Significant at $p < 0.001$; ANOVA

was a comparison of the county groups on the basis of the dependent variables, while controlling for the demographic covariates. The overall crime rate was higher in wet counties, but was not included in the analysis since several of the dependent variables were specific crimes related to alcohol abuse. Analysis of Covariance indicated that the differences between groups for total alcohol-related accidents and DUI arrests remained. Even when the covariates were considered, rates for these two variables were significantly higher in wet counties ($p < 0.05$). These data are shown in Table 3.

Table 2. Selected Demagraphic Characteristics af Wet vs Dry Kentucky Caunties (118), 1988

	Wet	Dry	F
Mean Caunty Papulatian	36,196.1	18,581.2	18.37
Papulatian/sq. mile	129.4	52.6	16.67
Persans/hausehald	2.78	2.78	0.006 (N.S.)
Hausehalds headed by females (%)	9.42	8.45	10.22
High School graduatian (%)	51.0	41.7	20.05
Callege graduatian (%)	9.41	6.84	20.05
Crime/100,000	2,433.8	1,356.7	36.11
Per capita incame	8,119.56	6,927.23	20.31
Median hausehald incame	13,906.74	11,489.86	22.06
Residents in paverty (%)	17.82	23.55	13.40

All variables significant ($p < 0.01$) except where nated

Table 3. Measures af Selected Undesirable Cansequences af Alcahal Abuse in Wet vs Dry Kentucky Caunties, 1988. (rates/100,000)

	Wet	Dry	F
Tatal alcahal related highway accidents	237.6	169.4	6.14*
Alcahal related highway accidents with fatalities	13.0	10.9	3.71
Alcahal related highway accidents with injuries	110.8	98.9	0.21
Persans killed in alcahal related highway accidents	20.8	12.7	1.71
Persans injured in alcahal related highway accidents	182.5	158.2	1.00
DUI arrests	1253.6	930.2	5.72*
Juvenile DUI arrests	31.9	31.3	0.02
Murder	14.56	8.52	0.58
Rape	19.53	30.25	0.14
Assault	220.83	124.06	0.00
Hamicide deaths	5.45	5.56	0.004
Cirrhasis deaths	7.37	7.66	1.89
Suicide deaths	13.1	12.44	0.61
Cangenital anamalies	6.58	4.88	0.81

ANCOVA, demographic variables included as cavariates (all differences insignificant except where nated)
*Significant at $p < 0.05$

Discussion

Study findings are limited in several ways. There is no direct measure of alcohol consumption, but only events that are often related to alcohol abuse. Second, there are undoubtedly limitations in reporting of these alcohol-related events. For example, there may be suicide deaths that are unrecognized or unreported. Police officers may not uniformly recognize or report alcohol-related accidents or crime. One experiment found that police officers had low levels of accuracy in assessing the intoxication of subjects; their error was usually underestimating intoxication.[11] There may particularly be differences between officers in wet versus dry counties in this regard, because of local political influences. Also, the data reported describe the location where alcohol-related accidents, crime, and mortality took place, not where the involved individuals lived. This is not a perfect reflection of how much people drink within the confines of their own county. Future analysis could also include road and highway miles per county and licensed drivers per county. It would also strengthen the conclusions of the study if findings were plotted over a period of several years, to demonstrate a consistent pattern.

While noting the above caveats, this study shows that most of the consequences of alcohol abuse are not more common in wet counties. The notable exceptions to the principle study finding are alcohol-related accidents and DUI arrests. These accidents are 40% higher and DUI arrests 35% higher in wet counties. Even when controlling for the demographic covariates, dry counties have significantly lower rates. Findings of this study do not explain why other variables, such as cirrhosis or homicide, known to be related to alcohol abuse, do not seem to be influenced by local alcohol prohibition.

Though this and other studies seem to indicate the effectiveness of local prohibition policy, it is unlikely that this prevention strategy will be implemented beyond those counties that are already dry. However, in Kentucky and other states with dry counties, "dry forces" can confidently support their position.

The findings of this study demonstrate some value in local alcohol prohibition as it effects highway safety. It is recommended that leadership more objectively examine this particular prevention strategy. The research question has not been answered unequivocally. Heretofore, positions in this regard have been largely based on

personal values. If the dry counties were free of bootleggers, and therefore truly dry, the benefits might be even more apparent.

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Tube Cecostomy for Obstructing Cancer of the Left Colon

McHenry S. Brewer, MD; R. Judson Brewer, MD

Tube cecostomy is generally looked upon with disfavor as an initial step in the treatment of obstructing cancer of the left colon. These lesions are most commonly treated with transverse colostomy, followed at a later date by resection of the tumor and, later still, colostomy closure.[1,2] Some have recommended primary resection of the tumor with or without anastomosis and with or without colostomy.[3] The reported morbidity and mortality figures for these methods of treatment are, for the most part, surprisingly and alarmingly high.[4,5] In a recent review by Buechter et al,[6] mortality rates ranged from 23% to 45%.

Clinical Material

This report is based on a study of seven patients who had tube cecostomy performed for obstructing cancers of the left colon. There were four females and three males. Ages ranged from 57 to 85. All patients had high degrees of obstruction with markedly distended bowel proximal to the tumor. All patients had a barium enema prior to cecostomy.

Methods

A right lower quadrant muscle splitting incision is used. The distended cecum usually bulges into the incision. An absorbable pursestring suture is placed superiorly in the wall of the cecum. A #18 needle is placed in the end of the suction tubing and inserted into the cecum through the pursestring (Fig 1). This usually results in the evacuation of a very large amount of gas from the colon, making the bowel much less tensely distended. This decreases the probability of fecal contamination when the bowel is opened for insertion of the tube. The needle is then removed and a small opening is made into the cecum. A #24 Foley catheter with a five cc bag (sterile drainage bag attached) is then inserted, the pursestring tied, and the bag inflated (Fig 2). The tube is then carefully buried in the wall of the cecum with the Witzel technique, using interrupted 4-0 silk sutures, creating a tunnel about five cm long (Fig 3). If omentum is available, it should be anchored over this suture line and around the tube. The cecum is not sutured to the parietal peritoneum. The incision is closed in layers, using absorbable sutures. The tube is brought out through the incision. It is fixed securely to the skin with a suture and with tape.

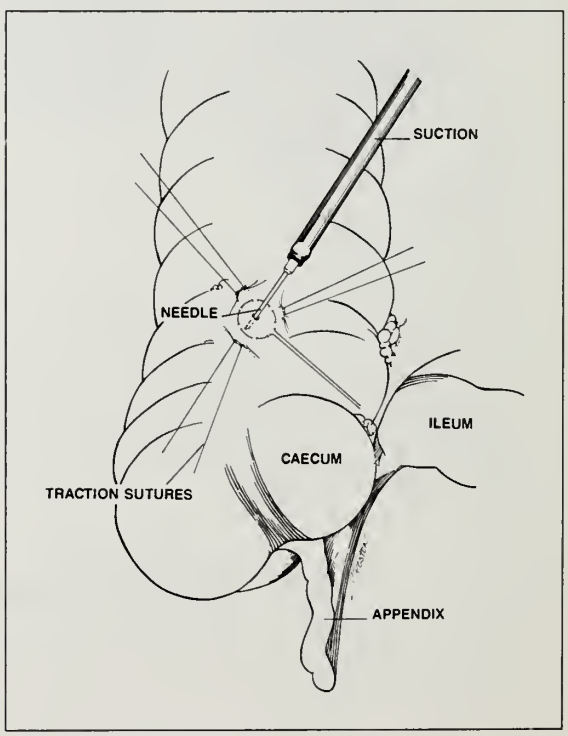


Fig 1

Post-op Care

The tube is attached to straight gravity drainage. One hundred fifty to 200 cc of tap water are instilled into the tube every 2 hours and the tube put back to drainage. At no time is suction applied to the tube. If suction is used, there is danger of obstructing the tube with solid fecal material.

Results

All patients had their obstructing cancers resected within 4 to 7 days (average 5.7) after the cecostomy was done. In all patients the preparation of the bowel was excellent at the time of resection.

There were no complications of any kind, either with the cecostomy or with the subsequent bowel resection. There were no wound infections and no anastomotic leaks. The patients were discharged from the hospital 8 to 17 days after bowel resection (average 11 days). The cecostomy tubes were removed from 8 to 20 days after bowel resection (average 13½ days). There was no fecal drainage around the tube in any patient nor was there any after removal of the tube. The average total hospital stay for these seven patients was 18 days. This is much shorter than usually required with other methods.

Five of the seven patients have had no recurrence of the cancer. Three are living without recurrent disease at 3, 3, and 8 years. Two have died of unrelated causes and without recurrent cancer at 12 and 6 years. One patient died with recurrent cancer at 1 year and another is alive with recurrent cancer at 1 year.

Discussion

Unacceptably high complication rates have been reported with tube cecostomy.[7-10] Our success is almost surely related to the technical details of performing the operation. Traditionally, large mushroom or Pezzar catheters, secured by pursestring sutures, have been used. The Foley catheter seems to work better. It may be that the inflated balloon in close proximity to the catheter opening helps maintain patency by holding the opening away from the mucosa. Removal of the Foley is certainly less traumatic than removal of a mushroom type catheter. *The most important technical detail* is burying the tube in the wall of the cecum with the Witzel technique. We feel that this prevents fecal leakage around the tube and

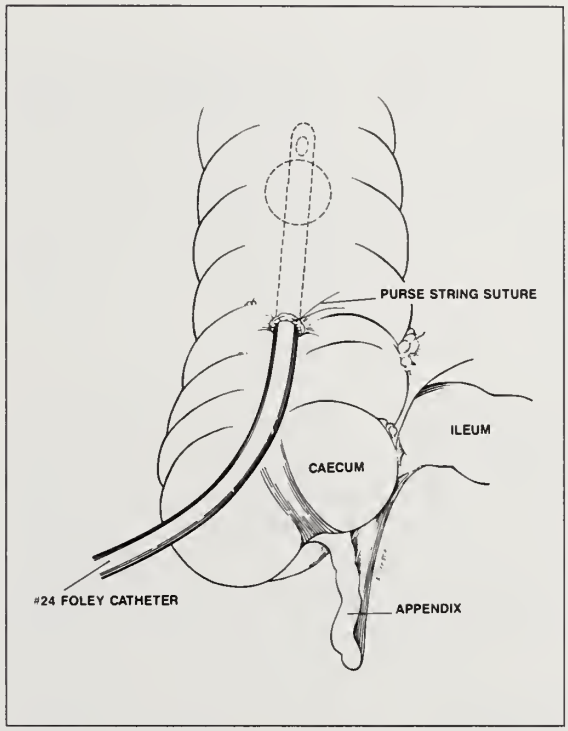


Fig 2

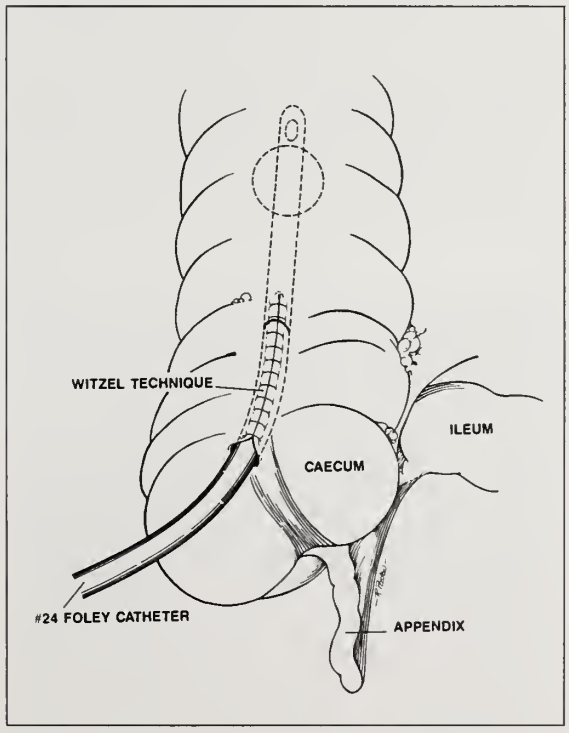


Fig 3

after removal of the tube.

Recent reports have described success with two methods: (1) subtotal colectomy with ileocolostomy[11,12] and (2) primary resection and anastomosis with intraoperative antegrade irrigation of the obstructed bowel.[13,14] Both methods involve the awkward necessity of extensive emergency surgery on a markedly distended and edematous bowel. Subtotal colectomy produces persistent diarrhea in a significant percent of patients. We believe preliminary tube cecostomy and early elective resection is preferable.

Conclusion

Tube cecostomy is a safe and effective method of bowel decompression in patients with obstructing cancers of the left colon.'The correct technical steps in performing the cecostomy must be followed. Good bowel preparation is rapidly achieved and early resection of the cancer can be done without complications.

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The Value and Limitation of Pleural Fluid pH Measurement

Archie J. Sanchez, MD; Thomas M. Roy, MD; Cheryl L. Fields, MD

Analysis of an aliquot of fluid from a pleural effusion will often provide the clinician with the information needed to establish a presumptive or definitive diagnosis of the patient's illness. A properly performed pleural fluid pH can maximize the diagnostic yield and provide guidelines for further clinical interventions.

From the Department of Respirotory ond Environmentol Medicine, Ambulotory Core Building, University of Louisville School of Medicine, Louisville, KY 40292.

Introduction

Determining the etiology of a patient's pleural effusion is a common clinical exercise that begins with the classification of the fluid as a transudate or an exudate. By using guidelines that employ the ratios of pleural fluid protein to serum protein and pleural fluid LDH to serum LDH, the physician can separate the causes of effusion into those due to hydrostatic and oncotic pressure imbalance and those due to serosal surface inflammation.[1]

If a transudate is present, a limited number of etiologies need be considered. On the other hand, the presence of an exudate requires closer scrutiny to narrow the wide spectrum of potential sources of pleural irritation. When a complete history and physical examination of the patient is combined with other routine chemical and microbiological tests of the pleural fluid, the etiology for approximately 80% of exudative effusions is apparent[2] (Table 1).

A number of ancillary tests including PO_2 and PCO_2, and pH have been proposed to increase the physician's ability to define the etiology of the 20% of unexplained exudative pleural effusions. While the value of measuring pleural fluid PO_2 and PCO_2 is minimal,[3] correct measurement of pleural fluid pH has emerged as a helpful diagnostic and prognostic index.

We present a patient with a perplexing pleural effusion with several potential etiologies. Pleural fluid pH measurement contributed to a greater understanding of her pleural pathology. The potential utility of pleural fluid pH measurement is described. The limitations of this measurement imposed by improper measuring techniques and specimen handling are also emphasized.

Case Report

The patient, a 60-year-old female, presented to the Pulmonary Clinic complaining of increasing dyspnea and chest pain of 2 weeks duration. The chest discomfort was diffuse and radiated to the retrosternal area and middle of the back. She also had developed a new cough that was productive of light yellow sputum. The patient denied hemoptysis or diaphoresis. She had lost her appetite for food and weighed 83 pounds at admission.

She had been diagnosed with squamous cell cancer of the right middle lobe 2 years earlier. The tumor had been treated with external radiation therapy, followed by brachytherapy with catheter guided isotope. She also had a diagnosis of chronic obstructive pulmonary disease that

Table 1. Camman Etialogies af Pleural Effusian

I. Transudative Pleural Effusians
Cangestive heart failure
Nephrotic syndrame
Cirrhosis
Hypothyroidism
Peritaneal dialysis
II. Exudative Pleural Effusions
Neoplasm
Infectian
Callagen vascular disease
Drug-induced
Pulmonary embolism
Gastraintestinal disease
Hematharax
Chylotharax

was treated with a beta-agonist and anticholinergic aerosols.

She was in moderate respiratory distress with a respiratory rate of 22/min and a heart rate of 116 beats per minute. Except for the chest evaluation, the remainder of her physical examination was normal. Breath sounds were decreased in the right posterior base. There was dullness to percussion and loss of tactile fremitus in this area.

Room air arterial blood gas analysis measured the pH at 7.47, the PaO_2 at 64 torr, and the $PaCO_2$ at 39 torr. Her serum sodium was decreased to 127 mEq/L and hemoglobin was decreased to 7.3 g/dl. Other laboratory studies were normal with an albumin of 3.3 g/dl.

Chest radiograph showed a right pleural effusion with air fluid levels suggesting communication with atmospheric pressure. Calcified granulomata were evident in the left hilum and left lung. The CT scan of the chest also demonstrated fluid and air in the pleural space consistent with a bronchopleural fistula. There were additional parenchymal opacities present that the radiologist felt were most consistent with a focal inflammatory process.

Based on the patient's history and imaging studies, the differential diagnosis for this condition included empyema, tuberculosis, granulomatous disease, and recurrence of bronchogenic neoplasm. A diagnostic thoracentesis with a measured pH was performed to better define the etiology of the pleural pathology. The pleural fluid was exudative and free of malignant cells. Gram stain was negative.

The pH of the pleural fluid, performed by pH meter, was reported as 8.6. This measurement is consistent with other case reports involving bronchopleural fistula associated with ammonia-producing *Proteus mirabilis*.[4] The culture failed to grow micro-organisms and repeat studies were requested. The patient, however, refused a second thoracentesis and declined a closed pleural biopsy.

Alternative explanations for her elevated pH value were investigated, but the manner in which the pleural fluid sample was handled and its pH determined were correct. The etiology of her effusion was presumed to be secondary to *Proteus*. She was discharged from the hospital with clinic appointment for follow-up.

Discussion

Initial studies of pleural fluid pH demonstrated that an exudate with a pH less than 7.30 was limited to six entities: tuberculosis, malignancy, hemothorax, complicated parapneumonic effusion (empyema), rheumatoid arthritis, and esophageal rupture. Good et al[5] further demonstrated that only the last three disorders were ever associated with a pleural fluid pH less than 7.0. This information, coupled with the white blood cell content of the pleural fluid, provides diagnostic clues to the etiology of the pleural fluid sequestration. In the context of a low pH, a white blood cell count with a mononuclear predominance is associated with malignancy, tuberculosis, and chronic rheumatoid disease. A polymorphonuclear cell differential suggests complicated parapneumonic effusion, esophageal rupture, and acute rheumatoid pleuritis.[5]

When the pleural fluid represents a parapneumonic effusion, the pleural fluid pH provides the clinician with vital information regarding the need for tube thoracoscopy to avoid pleural abscess.[6-8] In 1973, Light et al found evidence that patients whose parapneumonic effusion had a pH less than 7.20 respond poorly to the administration of antibiotics unless the pleural space is drained. On the other hand, similar patients with parapneumonic effusions whose pH was greater than 7.2 did well on appropriate antibiotics without chest tube drainage.[6] This observation was confirmed in later studies by Houston[7] and Potts[8] who demonstrated the tendency for parapneumonic effusions with a pH less than 7.20 to proceed to loculation with development of a chronic empyema. Patients with effusions that had pH values greater than 7.2 achieved cure with antibiotics and suffered no residual pleural problems. The cause of a low pleural fluid pH in complicated parapneumonic effusion is attributed to production of lactate and carbon dioxide as by-products of glucose metabolism by bacteria and leukocytes.[5]

The single exception to low pH in a complicated parapneumonic effusion has been reported in association with pleural fluid infected in urea-splitting *Proteus mirabilis*. Although normal pleural fluid pH may measure 7.6, values greater than this should be associated with either a *Proteus* infection that produces ammonia or inaccurate measuring techniques.[4]

Pleural fluid pH measurement may provide both prognostic and therapeutic information when an effusion is secondary to a neoplasm.[7,9] Malignant pleural effusions that have been present for longer than 3 months have a pH range of 7.04 to 7.29.[5] The pleural fluid pH suggests to the clinician the probability that neoplastic cells will

be found on cytologic examination of the fluid securing a diagnosis of a neoplastic process. Cytologic examination will be diagnostic on initial thoracentesis 50% of the time when the pH is greater than 7.30. If the pH is lower than this and is accompanied by a pleural fluid glucose less than 60 mg/dl, the diagnostic yield almost doubles to 90%.[10] The low pH and glucose values result from impaired glucose transport and acid efflux across a pleural membrane that has become fibrotic from tumor infiltration.[11]

Because malignant effusions have a tendency to be large, they may contribute to the cancer patient's discomfort by causing dyspnea. Removal of the fluid affords almost instant relief of the shortness of breath experienced at rest. Unfortunately, in most patients, the fluid will rapidly recur unless the pleural space can be obliterated by pleurodesis. Pleural fluid pH has proven to be a valuable predictor of successful pleurodesis in this situation. Eighty percent of patients whose malignant effusion has a pH greater than 7.30 have a successful pleurodesis that prevents reaccumulation of pleural fluid. In contrast, patients with a pleural fluid pH less than 7.30 have a 0% to 50% likelihood of successful pleural scarification.[7,9,10]

Palliative measures to combat malignant effusion should be weighed against the patient's long-term survival. The pleural fluid pH appears to have a strong correlation with the cancer patient's expected prognosis. The mean survival of a patient with a malignant effusion whose pH is greater than 7.30 is 7 to 10 months.[7] Those patients with bronchogenic carcinoma and a pleural pH less than 7.30 have an average life expectancy of only 4 to 8 weeks.[9] Aggressive therapy in this situation might be tempered and redirected toward patient comfort.

For a pleural fluid pH measurement to provide the clinician with meaningful information, the fluid must be handled in the appropriate manner. Pleural fluid is collected in a heparinized syringe (1,000 units/ml) and maintained anaerobically on ice.[4,5,8,9] In an anaerobic environment at 0° Celsius, minimal change in pleural fluid pH (+0.02) occurs for up to 8 hours.[6] On the other hand, pleural fluid allowed to sit at room temperature for 30 minutes will result in an alteration of the pH from an increase in PCO_2 as in vitro glycolysis proceeds.[5] The rate of pleural fluid pH decline at room temperature is proportional to the number of white blood cells in the specimen. The rate of CO_2 accumulation and pH change does not correlate with the initial PCO_2 or pH at the time of thoracentesis.[6]

It is important that physicians know how the pH value is measured in their hospital. Spurious values may occur in a properly handled specimen if faulty measurement techniques are employed. Accurate pleural fluid pH values can be objectively measured by either a pH meter or a blood gas machine. Attempts are also made at estimating pleural pH by using a urine pH dipstick. This method is the least accurate and most prone to error since it relies on a technician's subjective ability to detect subtle differences of color and shade. Unfortunately, in the Louisville area, 60% of hospitals surveyed use the less reliable urine dipstick method to estimate pleural fluid pH values. Approximately 30% of our hospitals measure pleural fluid pH with a blood gas analyzer, while 10% employ a pH meter.

In summary, the pleural fluid pH can provide insight into the etiology of an exudative effusion, provide guidelines for the use of tube thoracoscopy in parapneumonic effusions, predict patient response to pleurodesis in malignant effusions, and suggest mean survival in these patients. Despite its usefulness, the majority of community hospitals perform pleural fluid measurement no more than five times per year. We hope that this review will encourage greater interest in this parameter and promote its proper measuring technique.

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Cutis Marmorata Telangiectatica Congenita

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Cutis marmorata telangiectatica congenita (CMTC) is an uncommon benign condition presenting at birth with levido reticularis, telangiectasia, phlebectasia, and possible ulceration of the involved skin. Diagnosis is made through the clinical picture and supported by characteristic histopathologic changes when present. This condition should not be confused with manifestations of serious system disease and aggressive treatment is not indicated. We describe in this report a case of CMTC.

Introduction

Infants may be born with or develop a number of cutaneous manifestations in the neonatal period. These may range from harmless nevi to rashes presenting as part of a serious systemic disease. The primary care physician is faced with the dilemma of diagnosing and managing these conditions. Evaluation of uncommon skin anomalies may require the coordinated efforts of the primary care physician, dermatologist, plastic surgeon, and pathologist. In this article we report the clinical and diagnostic assessment of a child born with telangiectatic lesions.

Case Report

The female infant was the 3500 gram product of a 28-year-old G_1P_1 white female, term by dates and size. The prenatal course was complicated by a delay in diagnosing the pregnancy resulting in the mother receiving Prozac during the first 6 weeks of gestation. The mother also received antibiotic therapy early in the pregnancy for a tubal infection. The prenatal course was otherwise uncomplicated.

Labor lasted 10 hours and the membranes ruptured 8 hours prior to delivery. The infant was a low forceps vaginal delivery for outlet obstruction. Resuscitation was unremarkable; the infant received free flow oxygen. The Apgar score was 8 at 1 minute of age and 9 at 5 minutes of age.

The baby was noted to have multiple diffuse, reticulated, violaceous, telangiectatic lesions at birth. They were present on the abdomen, anterior and posterior chest, as well as the extensor surface of the extremities, hands and feet (Figs 1 and 2). The digits, head, face, and genitals were spared. The lesions blanched with pressure. There appeared to be loss of underlying subcutaneous tissue with atrophy of the skin. Except for the cutaneous findings, the child was normal. The liver and spleen were not enlarged, there was no evidence of hemihypertrophy, and no bruits were detected in the abdomen or over the orbits.

Admission laboratory studies included a white blood cell count of 13,300, hematocrit 50.9, neutrophil 47%, band 13%, lymphocyte 26%, monocyte 10%, eosinophil 4%, and platelet count of 268,000. The coagulation profile included a PT 12.1 (normal 10.6-11.9) and PTT 31.7 (normal 22-29). Routine surface cultures, blood, and suprapubic urine cultures were collected. All cultures proved to be negative for growth of organisms.

The baby had stable vital signs and breast fed well. Stool guaiacs were negative. Burrow's solution soaks were applied to the most severe areas on the legs. A punch biopsy was performed at two different lesions sites. They were both submitted for immunofluorescence studies. Pathology showed benign vascular proliferation in the mid reticular dermis consistent with a hemangioma.

Based on examination of the infant and review of the biopsy sections, the baby was diagnosed with Cutis marmorata telangiectatica congenita. The child has been seen for routine well child care. She continues to grow and develop normally; no anomalies have been noted. The

involved areas are fading and no additional lesions have developed.

Discussion

Cutis marmorata telangiectatica congenita is an uncommon cutaneous vascular condition also known as congenital generalized phlebectasia. It is present at birth and is striking with persistent, marked vascular mottling. It is an exaggerated response of the common Cutis marmorata seen in young children when their skin chills. Telangiectatacia, phlebectasia and skin ulcerations with crusting also occur.[1-3]

Associated congenital anomalies occur in as many as 50% of CMTC cases. Reported abnormalities include bone and subcutaneous atrophy and hypertrophy, Sturge-Weber syndrome, glaucoma patent ductus arteriosus, cleft palate, retinal detachment, dystrophic teeth, speech problems, syndactyly, delayed psychomotor development, mental retardation and poor growth.[1,3,4,5]

There is no known cause for CMTC. It occurs sporadically and results from some trigger for ectasia of capillaries and veins. Cutis marmorata telangiectatica congenita effects both sexes but may have a predisposition for females.[2-4]

The diagnosis of Cutis marmorata telangiectatica congenita is primarily accomplished by physical examination. Histopathologic changes may be variable, minimal, or nonspecific. However, the presence of dilated capillaries, large dilated veins in all layers of the dermis and subcutaneous tissue, as well as venous and capillary lakes in lesion biopsy sections supports the diagnosis of CMTC.[1,2]

The differential diagnosis for CMTC includes physiologic Cutis marmorata and diffuse phlebectasia of Brockenheimer (Brockenheimer syndrome).[6] Physiologic Cutis marmorata is a transient condition in infants. It is lighter in color than CMTC and results from chilling of the skin. Brockenheimer syndrome is not present at birth. It has gradual development of deep venous hemangiomas or hamartomas commonly on the limbs. These changes may develop at any time, from infancy through early adult life. Individuals with this condition may have a poor prognosis due to complications like cutaneous bleeding, infection, ulceration, thrombosis and gangrene.[6]

Children with CMTC generally show slow improvement over their first year of life.[7] This may be a direct result of growth and maturation of the dermis and epidermis. In severe cases the





Figs 1 & 2 — multiple cutaneous lesions.

manifestations may persist into adulthood. Treatment is directed towards minimizing complications from weeping skin lesions. Burrow's solution plus topical antibiotics may be applied to open areas. Systemic antibiotics may be required if secondary infections develop. It is important to maintain continued vigilance and evaluation for associated abnormalities.[2]

ACKNOWLEDGEMENT: The authors wish to thank Dr Anne Lucky at Children's Hospital Medical Center in Cincinnati, Ohio, for diagnosing this child.

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Men Are Not Cost Effective

Got your attention, didn't it? It certainly got mine.

Men Are Not Cost Effective is the title of a recently published book about crime in the United States by June Stephenson, PhD. Dr Stephenson's well researched book makes the point that the only crimes committed more commonly by females than males is prostitution, with greater than 90% of the violent crimes in the US being committed by men.

Today in the US, there are over one million male prisoners and 61 billion dollars is budgeted for prison care annually. Ironically, the most expensive prisoner is the one sentenced to death. The average cost to monitor a prisoner for life is $600,000 to $900,000. The average cost of a prisoner on death row is $4-5 million. Each appeal costs the taxpayers approximately $1,000,000, and in most states the prisoner is allowed six appeals.

Now, you are probably wondering why this is all being rehashed in a medical journal editorial. Allison Javin, PhD, Director of Harvard University School of Public Health Education Project, recently spoke at the University of Louisville Alumni Association Town and Gown dinner. Dr Javin pointed out that the leading cause of death in young males in this country is homicide. She further contrasted the major problems in California high schools today with the major problems in California schools even 20 years ago. In 1972, chewing gum, littering, and throwing spitballs were still cited as the major problems in the classroom. Currently, California high schools list carrying weapons and violent crime, drug use, alcoholism, unwed mothers and teenage pregnancy, and sexually transmitted diseases as the major problems. Dr Javin was proposing that a daily required educational course addressing these topics, taught by a registered nurse, be instituted nationwide beginning with the third or fourth grade. Sounds like a good idea and certainly a project worthy of the support of the medical profession. But after reading Dr Stephenson's book about men and crime where she explores in depth the factors leading to crime by males, it makes me wonder what else should we be doing to decrease violent crimes. In the last 5 years, juvenile crime has increased by 20%. The cost was 1.46 billion dollars. In many states, money needed for education and health are limited by the costs of prison care. As Dr Joyce Brothers writes, "The greater the level of exposure to TV violence the more the child is willing to use violence and see it as a solution to conflict."

"Isn't it time we in the medical profession strengthen our resolves to decrease crime and violence and develop a systematic aggressive means of bringing pressure on TV producers, directors, and sponsors to realize the importance of controlling violence on TV."

To quote Dr Stephenson:

> Studies have shown that by 16 years of age a typical child through movies and TV has been exposed to approximately 33,000 murders and over 200,000 acts of other violence. What becomes the reality for children? Movies are becoming more violent and so is TV. Movies now show rape, murder, and female mutilation as in *The Silence of the Lambs*.
>
> This violence-viewing starts with Saturday morning comics with continual acts of destruction. The victims are never shown to suffer. There is nothing for the child to empathize with except the victory of the conqueror over the vanquished. Comic books show women in bondage in full color.
>
> A new law, signed by President Bush in December 1990, gives television stations immunity from antitrust laws if they should meet to discuss how to set standards on reducing the violence on their programs. As the vice president of CBS said, "It is a well-intentioned effort on Congress' part, but this is a problem that is not easily solved." People who keep track of violence on TV maintain that programs are now twice as violent as they were 10 years ago. It is claimed by the National Coalition on Television Violence that prime-time television programs presented an average of 10 violent acts per hour in 1990. In an effort to limit violence on TV, there is the argument that First

Amendment rights of free speech are being violated. TV is only one of the mediums [sic] which influence people, but watching TV is a major time consumer for many children.

On a recent trip to Honduras, I was struck by the fact that even in the barrios composed of houses with board walls, tin roofs, no floors, doors, windows or running water, every house had TV. How can 1 hour a day of classroom education compete with the impact of 6 to 8 hours of glamorized sex, violence, and alcohol shown on TV?

Rape, one of the violent crimes on the increase, was reported last week in my neighborhood. The victim was a 5-year-old girl abducted from her front porch.

Year after year, resolutions are passed at our state and national society meetings against violence on TV. "Of course we're against violence!" seems to be the attitude and then nothing further is done.

Dr Stephenson showed studies of other factors which influence violent male behavior including learning disabilities, poverty, emotional problems, and dysfunctional families. We are doing very little to address the leading cause of death in young males, a recognized public health problem. We may not be able to alleviate all of these factors, but we can assist in identifying individual patients and families with these problems and referring them for appropriate counseling and assistance. And isn't it time we in the medical profession strengthen our resolves to decrease crime and violence and develop a systematic aggressive means of bringing pressure on TV producers, directors, and sponsors to realize the importance of controlling violence on TV. We can't afford not to. Crime is not cost effective.

Jannice O. Aaron, MD

Help for Impaired Physicians

Through its Committee on Impaired Physicians, KMA helps doctors who are suffering from alcoholism and drug addiction. The thrust of the program is rehabilitative, not punitive. The Committee is composed of physicians who have special expertise in these areas, some from personal experience. Effective treatment for these illnesses is achieved most easily when the disease is detected early; family, friends, and associates are urged to avoid misguided sympathy which enables the condition to deteriorate.

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

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Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

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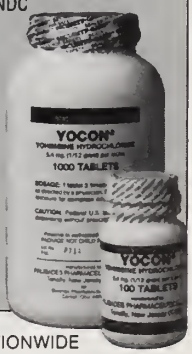
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

Rev. 1/85

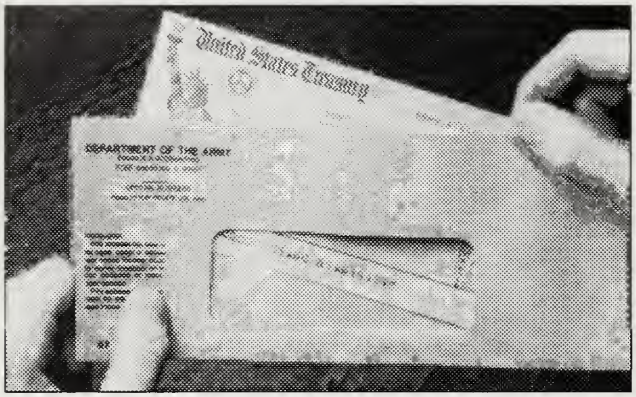


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A Call for Nutritional Training

TO THE EDITOR: Preventive medicine continues to bring a greater emphasis on nutrition. In fact, proper nutrition is often linked to prevention of disease. The heralded Framingham study, which has shown the risk factors of cardiovascular and cerebrovascular disease, includes dietary intake as a major influencing factor. This same study notes that nutritional training in medical schools, internships, and residency programs is inadequate.[1] Even with these reports, nutritional education remains a very obscure part of medical curriculum.

In 1985, the National Research Council found that most medical students receive less than adequate training in nutrition. They found that faculty generally believe the following clinical competencies as most important: use of enteral and parenteral feeding techniques in patient therapy, the improvement of fluid and electrolyte imbalances, and knowledge of the role of nutrition in the identification and management of selected disease states. Preclinical emphasis was placed on food sources of selected nutrients, properties of essential nutrients, and metabolic pathways involved in digestion, absorption and utilization in a mixed meal.[2] We feel this preclinical training will insure an interest and concern for patient status during the clinical years.

In a 1991 poll of 105 third year, clinical phase students, 69.5% believed it would be helpful if departments other than Family Practice would have a segment of their clerkship devoted to nutrition.[3] In a more recent poll of 101 second year medical students, we found that 84.0% feel they are not receiving enough training in the area of nutrition.

Failure to instruct patients in the area of nutrition can result in their return to deleterious lifestyles.[4] Consequently, the quality of health care is jeopardized. The public does have an interest in nutrition and its relation to health and disease. However, this same public believes that physicians lack sufficient knowledge of the subject.[5] In fact, physicians will often be the first to admit their ignorance in the area of nutrition. Therefore, nutritional education will not only have an impact on patient care, but will also improve the health status of medical professionals.

Lack of time, money, and resources are all reasons given for the justification of nutritional ignorance.[6] We do not ask that new courses be added to the medical students' already heavy workload. We simply propose a more thorough incorporation of nutritional information in the present medical school curriculum. Nutrition affects all areas of medical study and until this relationship is appreciated, ignorance of the subject is forced to continue.

John T. Stutts, BS
Morton L. Kasdan, MD, FACS

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RATES AND DATA

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Word count: Count as one word all single words, two initials of a name, single numbers or groups of numbers, hyphenated words, and abbreviations.

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RURAL KENTUCKY MEDICAL SCHOLARSHIP FUND

The Rural Kentucky Medical Scholarship Fund is accepting applications from residents of Kentucky, who have been accepted at the University of Kentucky College of Medicine or the University of Louisville Medical School. The Fund offers a $10,000 loan for each year of medical school to a qualified recipient who is willing to practice and reside in a rural county in Kentucky for one year for each loan received. The interest rate is determined on May 1. Repayment options include low interest rates for recipients practicing in rural areas and loan forgiveness for those practicing in areas of the state with critical needs. The Fund is the oldest and most successful of its kind in the nation. The Rural Kentucky Medical Scholarship Fund has loaned approximately $3 million to over 550 medical students. The deadline date for filing an application is **April 1.** Those interested in applying for a scholarship loan should contact the RKMSF Office at the Kentucky Medical Association Headquarters, 301 N Hurstbourne Parkway, Suite 200, Louisville, KY 40222, or call 502/426-6200.



Beryl Dodds

Invest in the Future of Medicine

Many factors contribute to the high standard of medical care in the United States. Among them is the expertise of the physicians providing that care. The American Medical Association Education and Research Foundation (AMA-ERF) is a non-profit, public foundation dedicated to ensuring that medical schools and students receive funds to supplement the cost of high quality education and training.

AMA-ERF currently has several funds — The Development Fund, the Categorical Research Grant Fund, the Medical Student Assistance Fund, and the Medical School Excellence Fund.

The Development Fund is used at the discretion of the AMA-ERF Board of Directors to support pilot and experimental health and medical programs. The Categorical Research Grant Fund (CRGF) is used for specific research areas.

The Medical Student Assistance Fund has averaged over $500,000 each year since its creation in 1983. This fund provides grants to medical schools for direct financial assistance to students. The specific financial aid programs vary with the individual medical schools. The only requirement is that the school use the funds to support educational expenses of medical students with a recognized need.

The Medical School Excellence Fund is the oldest and largest of the funds. Since its beginning, over $47 million has been given to medical schools. Across the country, these unrestricted funds have been used to support programs for women and minority medical students and to pay for publications, computer software, and other equipment. It is also used to fund student activities, research programs, guest lecturers, and student attendance at national meetings and conferences.

This past year at the University of Kentucky, $6,000 from AMA-ERF was used to provide scholarships for medical students in need. Additional money was used to provide CPR training for first year students; purchase a cardiac sound machine and biochemistry software; develop software for use in the basic sciences; and purchase equipment and supplies for a free clinic at the Salvation Army. The free clinic is staffed on a volunteer basis by approximately 125 medical students and 25 faculty.

At the University of Louisville, $16,000 of AMA-ERF money was spent on summer research scholars. These students, usually first or second year students, work on research projects with a faculty member during the summer. Without these unrestricted funds, this type of enrichment would be impossible. Another $17,000 was used for scholarship support. Scholarships were awarded based not only on need, but also on academic excellence.

Since 1951, AMA-ERF has given over $53 million to medical schools, consistently supporting quality medical education in the United States.

Last year the AMA Auxiliary once again broke the $2 million mark.

"Support the American Medical Association Education and Research Foundation and invest in the future of medicine in America."

Proceeds from state and county fundraisers were up 3.3% over 1990. In 1991-92 the Auxiliary to the Kentucky Medical Association raised $54,151.33. Physician contributions were $2,305, for a total of $56,456.33.

The Boyd County Medical Auxiliary was second in the nation in per capita contributions with $192.76 per member. My congratulations to Boyd County.

I'd like to encourage you to support the medical school of your choice by contributing to AMA-ERF. To contribute through the Auxiliary to the KMA, send your check, made out to AMA-ERF, to Karen Raque (George), 508 Kinglan Road, Louisville, KY 40207. For contributions of $100 or more, ask Karen for a direct contribution. In this case, after being routed through the Foundation office in Chicago, the contribution will be sent directly to the medical school with immediate credit for the donor (for Century Clubs, etc). Please be sure to designate the medical school and either the Medical Student Assistance Fund or the Medical School Excellence Fund.

Support the American Medical Association Education and Research Foundation and invest in the future of medicine in America.

Beryl Dodds

AKMA President

1993

FEBRUARY

7-11 — Southeastern Surgical Congress Annual Meeting; Tarpon Springs, FL. Contact: Southeastern Surgical Congress, 1776 Peachtree St, NW, Suite 4010N, Atlanta, GA 30309; 404/607-8958.

MARCH

6-13 — Update in Clinical Medicine; Vail, Colorado. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037, 202/994-4285 (phone), 202/994-1791 (fax).

MAY

7-8 — The Virginia Society of Otolaryngology-HNS Annual Meeting; Tides Inn Resort, Irvington, VA. Contact: Donna Scott, 4205 Dover Rd, Richmond, VA 23221; 804/353-2721.

13-16 — Central Atlantic Seminar in Anesthesiology; Washington, DC. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037, 202/994-4285 (phone), 202/994-1791 (fax).

JUNE

10-12 — 38th Great Smoky Mountains Pediatric Seminar; Park Vista Hotel, Gatlinburg, TN. Contact: CME, 1924 Alcoa Highway, D-116, Knoxville, TN 37920; 615/544-9190.

SEPTEMBER

18 — Tenth Annual Ophthalmology Seminar: Update on Management of Age-Related Macular Degeneration; Humana Hospital Audubon, Louisville, KY. Contact: Cathy Edens, 240 Audubon Medical Plaza, Louisville, KY 40217; 502/636-2823.

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PRACTICE MANAGEMENT SEMINARS

The Kentucky Medical Association, in conjunction with a number of county medical societies, will sponsor the following seminars in 1993:

January

Gearing Up For Retirement
Jan 20 - Louisville

February

Profitable Practice
16 - Louisville
17 - Lexington

Reception Techniques/Better Collections
18 - Lexington

CPT Coding
23 - Northern Kentucky
24 - Lexington
25 - Louisville

Financial Control of Your Practice in 30 Minutes
24 - Lexington (2-hour seminar)
26 - Louisville (2-hour seminar)

March

Marketing Techniques
10 - Northern Kentucky
11 - Louisville

How To Get Started in Practice
12 - Louisville

For more information on these workshops, contact:
Kentucky Medical Association
(502) 426-6200

PEOPLE

Robert R. Goodin, MD, Louisville, has been appointed by the AMA Board of Trustees to the AMA Continuing Medical Education Advisory Committee for the calendar year 1993. Dr Goodin is a member of the KMA Committee on Continuing Medical Education. He also serves as Chairman of the Physician Manpower Committee, a member of the Board of Trustees, and an AMA Delegate.

Past KMA President **Bob M. DeWeese, MD,** won a landslide victory on November 3 for the seat as representative of Kentucky's 48th District. Dr DeWeese takes over the seat of Representative Susan Stokes, who ran for Congress this year. Mrs Stokes is the wife of **Lowell L. Stokes, MD.**

Doctor DeWeese will take office this month as a state representative in Frankfort.

Stephen L. Henry, MD, Louisville, was elected Jefferson County District Commissioner in November.

Dr Henry is a faculty member in the Department of Orthopaedic Surgery at the University of Louisville School of Medicine.

Edward A. Luce, MD, professor of surgery at the University of Kentucky College of Medicine, was recently elected president of the Southeastern Society of Plastic and Reconstructive Surgeons, a regional society of approximately 500 plastic surgeons.

UK advises that Dr Luce is the immediate past president of the American Society of Maxillofacial Surgeons and immediate past chairman of the American Board of Plastic Surgery. Also, in 1990 he was named "Clinician of the Year" by the American Association of Plastic Surgeons, and in January 1992 he was one of seven UK physicians to be named to the "Best Doctors in America" list.

Yosh Maruyama, MD, professor of radiation medicine, University of Kentucky, was one of the Keynote speakers at the International Conference on "Neutrons in Cancer Therapy: 60th Anniversary of the Discovery of the Neutron" held at Trinity College, Cambridge University, England. The meeting celebrated the 60th anniversary of the Nobel prize discovery of the neutron and its application to radiation cancer medicine. Dr Maruyama is internationally acclaimed for his research on Cf-252 for neutron therapy.

Norman M. Cole, MD, recently concluded his term as the 52nd president of the American Society of Plastic and Reconstructive Surgeons (ASPRS).

Following inauguration as president, Dr Cole immediately faced a major crisis in the specialty, involving a possible ban of breast implants by the FDA. Under his leadership, the 4,500-member Society passed a special, mandatory member assessment to help educate the public and Congress about the need to keep breast implants on the market. Dr Cole and several ASPRS officials helped organize a Washington, DC, fly-in, which received national media coverage and activated more than 600 patients and plastic surgeons who alerted Congress to the urgent need to help keep breast implants available to the women who want them

UPDATES

Dates and Format Changed for CPT Coding Workshops

The CPT Coding Workshops, previously scheduled as half-day sessions on January 26-28, have been changed to February 23 (Northern Kentucky), February 24 (Lexington) and February 25 (Louisville). The AMA, which is conducting the workshops, has revised the program to a full-day format and to better meet the needs of attendees. Registration brochures will be mailed from KMA in early 1993.

Breast Cancer Registry for Indigent Women

The 1990 General Assembly passed Senate Bill 41 to provide breast and cervical cancer screening "where it is not otherwise readily available for reasons of cost or distance to suitable health care facilities." Key elements of the Bill included:

- Establishment of the program within the Department for Health Services and creation of a special fund to be used for breast cancer screening.
- "Screening" services to "asymptomatic" women. Funds are not to be used for purposes of diagnosis or treatment.
- Creation of a Breast Cancer Advisory Committee to advise the Commissioner of the Department for Health Services on guidelines for the breast cancer screening program.

The major change in the Cancer and Family Planning programs has been expanded breast cancer screening, including mammography. Screening of low income women has been the first priority because of the large number of women who are not currently being screened. Approximately 20% of Kentucky women, or 748,000, are over 40 years of age and should be receiving regular screening for breast cancer.

The initial criteria for eligibility included women 45 years of age and older at or below 185% of the poverty level who had never had a

mammogram. Those requirements have been broadened to fit the age and frequency guidelines of the American Cancer Society, National Cancer Institute, and other organizations. Now women who meet the income guidelines are eligible for a screening mammogram as follows:

- Baseline: Ages 35 through 39
- Every one to two years: Ages 40 through 49
- Annual: Ages 50 and older

With the support of the Kentucky Chapter of the American College of Radiology, the Department of Health Services has developed a model contract for screening mammography, including interpretation. The cost to the program is $50 per screening.

The KMA Cancer Committee, in a recent report to the Board of Trustees, recommended that physicians be encouraged to refer low-income women to their local health departments so that more Kentucky women will receive regular screening mammograms. The Board of Trustees also encourages radiologists to contract with their local health departments for women to receive screening mammograms.

UK Awarded Contract for National AIDS Information Project

The University of Kentucky College of Medicine's Department of Preventive Medicine and Environmental Health has been awarded a $70,000 1-year contract from the Health Resources and Services Administration of the US Department of Health and Human Services to research information networks about AIDS and HIV disease among physicians, dentists, and other health care professionals.

The project involves the educational programs and publications of the 17 federally funded AIDS Education and Training Centers (AETCs). **Terence Collins, MD,** professor of preventive medicine and environmental health, will co-direct the contract with Judy Stephenson, project coordinator of the East Central AETC. According to Ms Stephenson, the contract is the first attempt by a federal agency to study how HIV/AIDS information for health care professionals is being collected and distributed across the US, Virgin Islands, and Puerto Rico.

"We are working to improve the transfer of information from federally funded agencies to health care practitioners in the field," she said. "Information about HIV disease undergoes frequent and rapid change. It is important that health care professionals have the most current information to treat and care for patients with HIV disease."

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Barren

William E. Holcomb, II, MD — OPH
107 Sandwood Dr, Glasgow 42141
1986, Medical College of Alabama

Boyd

Michael D. Canty, MD — GE
1033 Ashland Avenue, Ashland 41101
1981, Medical U of South Carolina

Ralph C. Hess, III, DO — EM
6916 Hickory Hills Dr, Ashland 41102
1980, WV School of Osteopathic Medicine

Edwin J. Seligson, MD — IM
2128 Hilton Ave, Ashland 41101
1962, U of California, Irvine

Bjorn Thorarinsson, MD — PUD
615 Amanda Furnace Dr, Ashland 41101
1976, U of Iceland

Boyle

Jonathan E. Ricker, MD — PD
303 S 4th St, Danville 40422
1989, U of Texas, Dallas

Christian

David H. Leeper, MD — P
1967 Stepford Dr, Clarksville, TN 37043
1966, U of Kentucky

Clay

Tanvir M. Dara, MD — IM
RR 5 Box 422, Manchester, 40962
1985, King Edward Med School, Pakistan

Fayette

Wendy M. Collini, MD — IM
515 Laketower Dr #531, Lexington 40502
1988, U of Texas, Houston

Terrence R. Grimm, MD — S
2368 Nicholasville Rd, Lexington 40503
1987, U of Kentucky

Sandra Kay Haigler, MD — AN
3320 Tates Creek Rd, Lexington 40502
1980, U of North Carolina

Martha Jane Post, MD — D
2157 Broadhead Pl, Lexington 40515
1984, U of Louisville

John G. Roth, MD — D
177 Burt Rd, Lexington 40503
1988, U of Louisville

Janet L. Walker, MD — ORS
1900 Richmond Rd, Lexington 40502
1981, U of Southern Florida

Franklin

John R. Howard, MD — S
306 Cedarbook Ct, Frankfort 40601
1986, U of Louisville

Hardin

Stewart M. Couch, MD — R
P O Box 2049, Elizabethtown 42702
1988, U of Kentucky

Rita R. Ellithorpe, MD -FP
1210 Lyndon Lane, Radcliff 40160
1982, Chicago Medical School

Norma J. Guzman, MD — PD
104 Poplar Cir #512, Radcliff 40160
1982, Ponce School of Med, Puerto Rico

Thomas G. Ingram, MD — FP
1239 Woodland Dr, Elizabethtown 42701
1989, U of Kentucky

Steven R. Vallance, MD — S
2 Oakwood Dr, Vine Grove 40175
1987, U of Kentucky

Henderson

John F. Elenewski, MD — AN
1305 N Elm St, Henderson 42420
1978, U of Guadalajara

Deborah S. Wayne, DO — FP
319 8th St, Henderson 42420
1989, Col of Osteopathic Med, Kansas City

Jefferson

Paul K. Gardner, MD — NS
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1985, Duke University

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1980, Government Medical Col, India

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1984, Tulane University

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1984, U of Louisville

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1976, Case Western Reserve

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1983, U of Illinois

Owen

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1991, U of Louisville

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1988, U of Kentucky

Lynne W. Stockman, DO — FP
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1989, Ohio U of Osteopathic Medicine

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Fayette

Stephen K. Reed, MD — C
John B. Sanders, MD — AN
Sheila P. Sanders, MD — OPH

Jefferson

J. Samuel Buck, MD — OBG
Jason Dorey, MD — R

Northern Kentucky

Daniel J. Barkdoll, MD — FP
Gina B. Grove, MD — FP
Todd G. Prewitt, MD — FP

DEATHS

Ruel T. Routt, MD
Jamestown
1911-1992

Ruel T. Routt, MD, a retired general practitioner, died August 31, 1992. He graduated from the University of Louisville School of Medicine in 1937 and was a life member of KMA.

James E. VanHoose, MD
Wheelwright
1929-1992

James E. VanHoose, MD, a general practitioner, died October 4, 1992. Dr VanHoose graduated from the University of Louisville School of Medicine in 1959 and was an active member of KMA.

Lawrence O. Toomey, MD
Bowling Green
1903-1992

Lawrence O. Toomey, MD, a retired internist, died October 6, 1992. Dr Toomey graduated from the University of Louisville School of Medicine in 1930 and was a life member of KMA.

Caleb H. Chu, MD
London
1913-1992

Caleb H. Chu, MD, a retired surgeon, died October 17, 1992. As one of the original physicians to open the Oneida Mountain Hospital in 1956, and as an active participant in the development of Memorial Hospital in Manchester, Dr Chu devoted his life to serving the medical needs of the people of Eastern Kentucky. A 1942 graduate of National Defense Center in China, Dr Chu was a life member of KMA.

Charles D. Clark, MD
Murray
1924-1992

Charles D. Clark, MD, a family practitioner, died October 18, 1992. Dr Clark graduated from the University of Tennessee College of Medicine in 1950 as was an active member of KMA.

Fredrick J. Cecil, MD
Horse Cave
1926-1992

Fredrick J. Cecil, MD, a surgeon, died October 21, 1992. A 1954 graduate of the University of Louisville School of Medicine, Dr Cecil was an active member of KMA.

Robert E. Reichert, MD
Covington
1907-1992

Robert E. Reichert, MD, a retired surgeon, died October 23, 1992. Dr Reichert graduated from the University of Cincinnati College of Medicine in 1932 and was a life member of KMA.

Mary L. Osborne, MD
Louisville
1929-1992

Mary L. Osborne, MD, a rheumatologist, died October 28, 1992. Dr Osborne graduated from the University of Louisville School of Medicine in 1963 and was an active member of KMA.

Charles R. Fisher, MD
Madisonville
1922-1992

Charles R. Fisher, MD, a family practitioner, died November 14, 1992. Dr Fisher was a 1953 graduate of the University of Louisville School of Medicine and has been a member of KMA since 1955.

Carl T. Clark, MD
Lexington
1896-1992

Carl T. Clark, MD, a retired general practitioner, died November 15, 1992. A graduate of the University of Louisville School of Medicine in 1931, Dr Clark was a life member of KMA.

Steven W. Kimbell, MD
Henderson
1940-1992

Steven W. Kimbell, MD, a psychiatrist, died November 15, 1992. Dr Kimbell graduated from the University of Louisville School of Medicine in 1975 and was an active member of KMA.

Robert N. McLeod, MD
Somerset
1921-1992

Robert N. McLeod, MD, a retired pediatrician known for his work in sports medicine, died November 17, 1992. Dr McLeod was instrumental in establishing an annual sports medicine symposium for coaches, trainers, and doctors involved in state high school athletics. He also had been the official doctor for the state's Sweet 16 Basketball Tournament. Dr McLeod was a 1945 graduate of the University of Pennsylvania School of Medicine and a life member of KMA.

Charles H. Blandford, MD
Lyndon
1905-1992

Charles H. Blandford, MD, a retired general practitioner, died November 23, 1992. A 1929 graduate of the University of Louisville School of Medicine, Dr Blandford was a life member of KMA.

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of preganglionic fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions**.)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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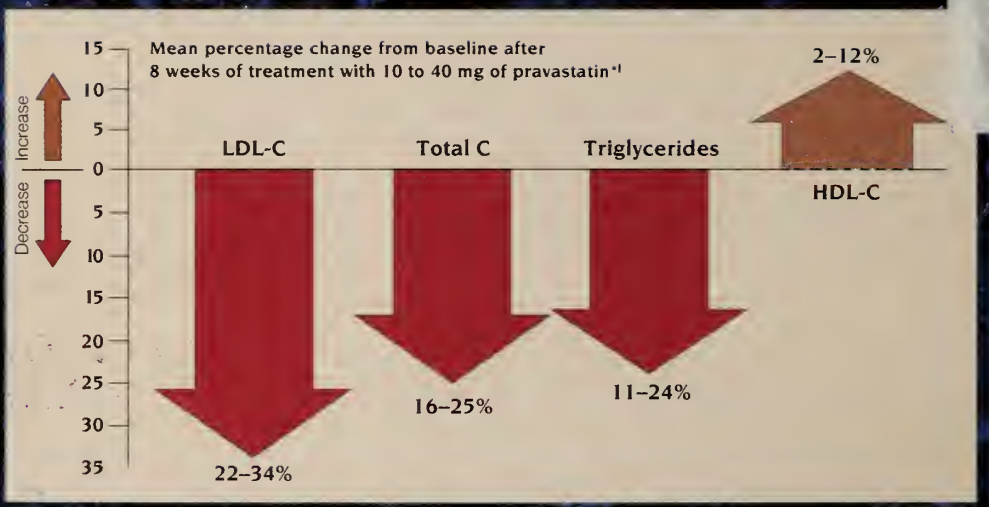
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL™

pravastatin sodium 20 mg tablets

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

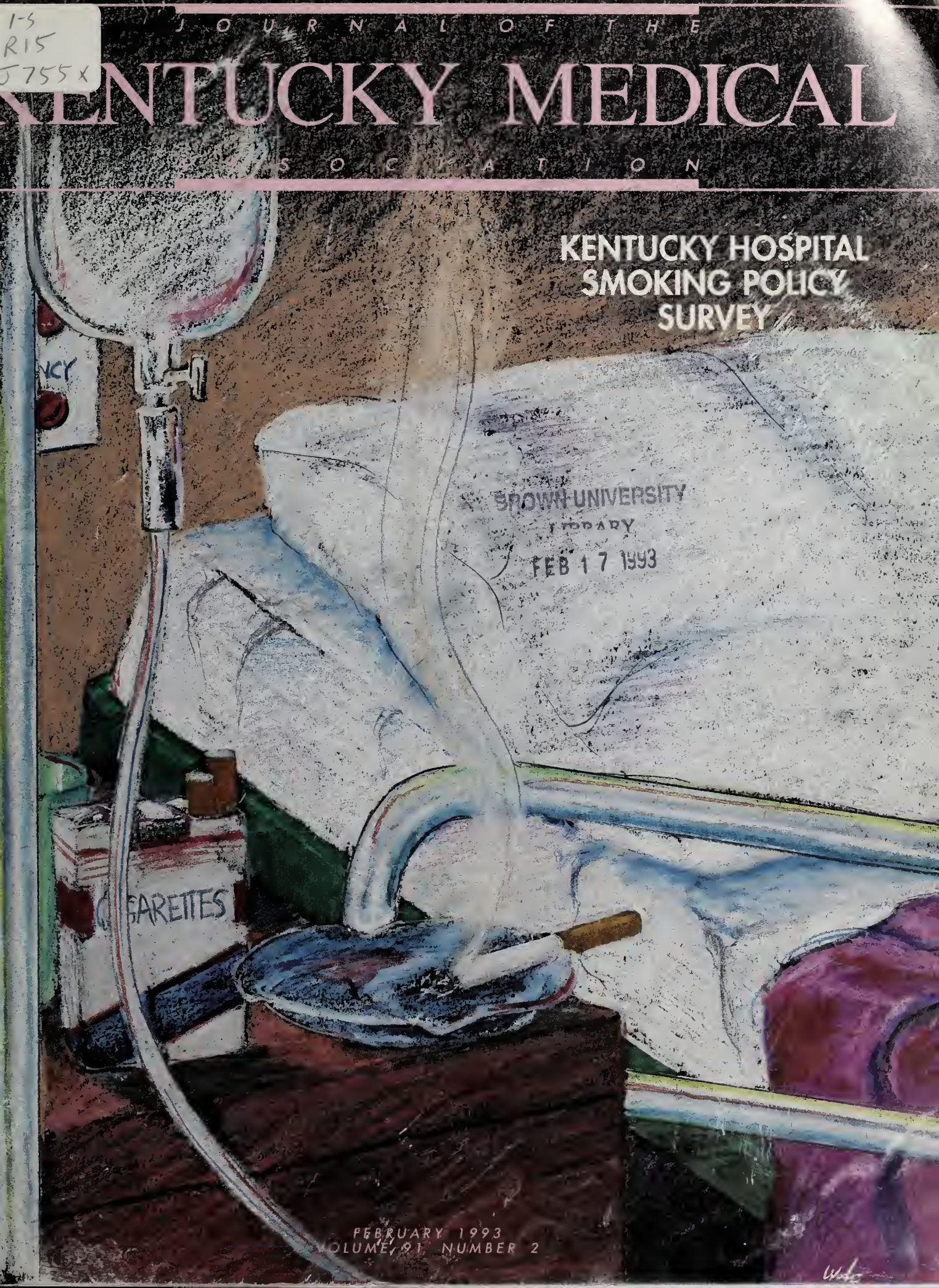
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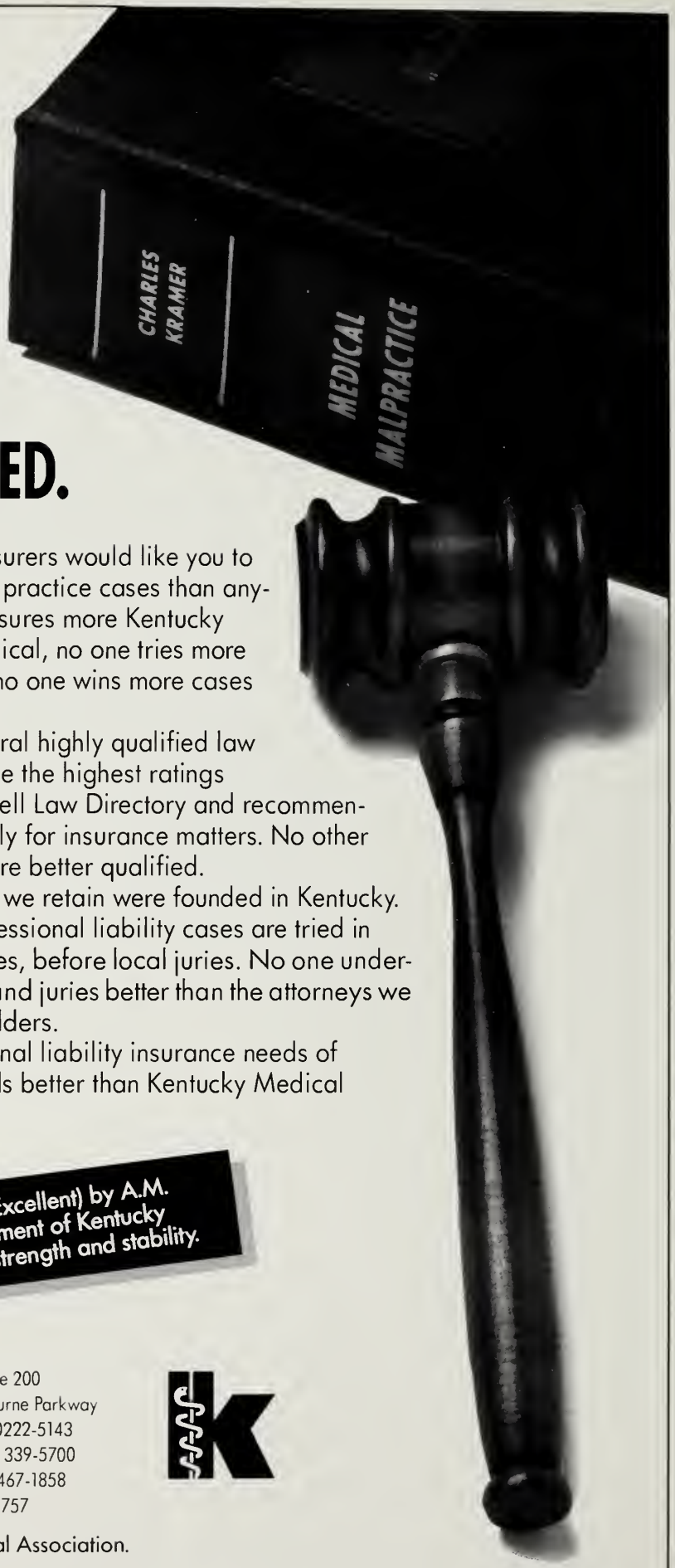


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***COVER:** This month's cover story presents a follow-up haspital smaking policy survey. The initial report was featured in the March 1990 issue of the Journal. Illustratian and design by Lee Wade af Lauisville.*

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The Physician: The Patient Advocate



Ardis D. Hoven, MD

We have entered a new year in which great emphasis will continue to be placed on health care and health systems reform. The potential for change and perhaps some loss of physician autonomy are of concern to each of us. As physicians in our daily role as caregivers, we frequently must speak out on a great number of issues related to quality patient care. It is imperative that we as physicians continue to make our role as patient advocates a priority in these critical times. Organized medicine and all physicians in the state of Kentucky have strengthened and should continue to strengthen the patient advocacy role.

As patient advocates, family and interpersonal violence continues to be a major agenda item for members of the Kentucky Medical Association. Steps have been taken to strengthen the physician's ability to recognize and deal with elder abuse, spouse abuse, and child abuse. We have recently learned that in this state, adult abuse cases have increased by 37.5% compared to 1991. Efforts at all levels are beginning to reveal the true incidence of this problem.

As patient advocates, we must also speak strongly for quality medical care, and the assurance of access to quality medical care. Health systems reform will force us to keenly look at the issues and address them in a manner that allows us to determine whether or not it is in the best interest of our patients. In meetings with physicians I repeatedly hear of their concern for such issues and the impact that health care reform will have on the quality of health care.

As patient advocates, we are obligated to pursue and help solve the problems related to nonhealthy life-styles. Alcohol and tobacco abuse, substance abuse, and inadequate nutrition, to name a few, require active physician involvement and, frequently, willingness to participate and speak out at the community level. Many of you have already invested a great deal of time and intellectual effort in this area, and I encourage all physicians to make healthy life-styles a priority for their individual communities.

As patient advocates dedicated to quality health care, we likewise must continue to oversee and regulate ourselves, educate each other and provide educational resources, and carfully look at such matters as self referral, impaired or potentially impaired physicians, and other ethical issues. Perhaps these are not items we characteristically see as representing patient advocacy, but in fact who and what we are and how we practice medicine delineates in some part our role as advocates.

There are many other areas which could be addressed; however, let us continue to be a strong voice and a unified voice in our role as patient advocates.

Ardis D. Hoven, MD
KMA President-Elect

"It is imperative that we as physicians continue to make our role as patient advocates a priority in these critical times. Organized medicine and all physicians in the state of Kentucky have strengthened and should continue to strengthen the patient advocacy role."

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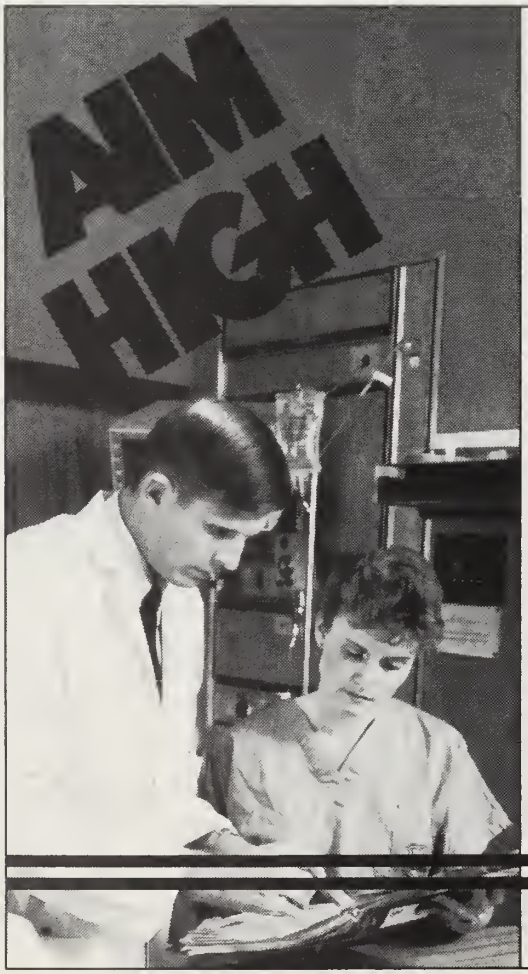
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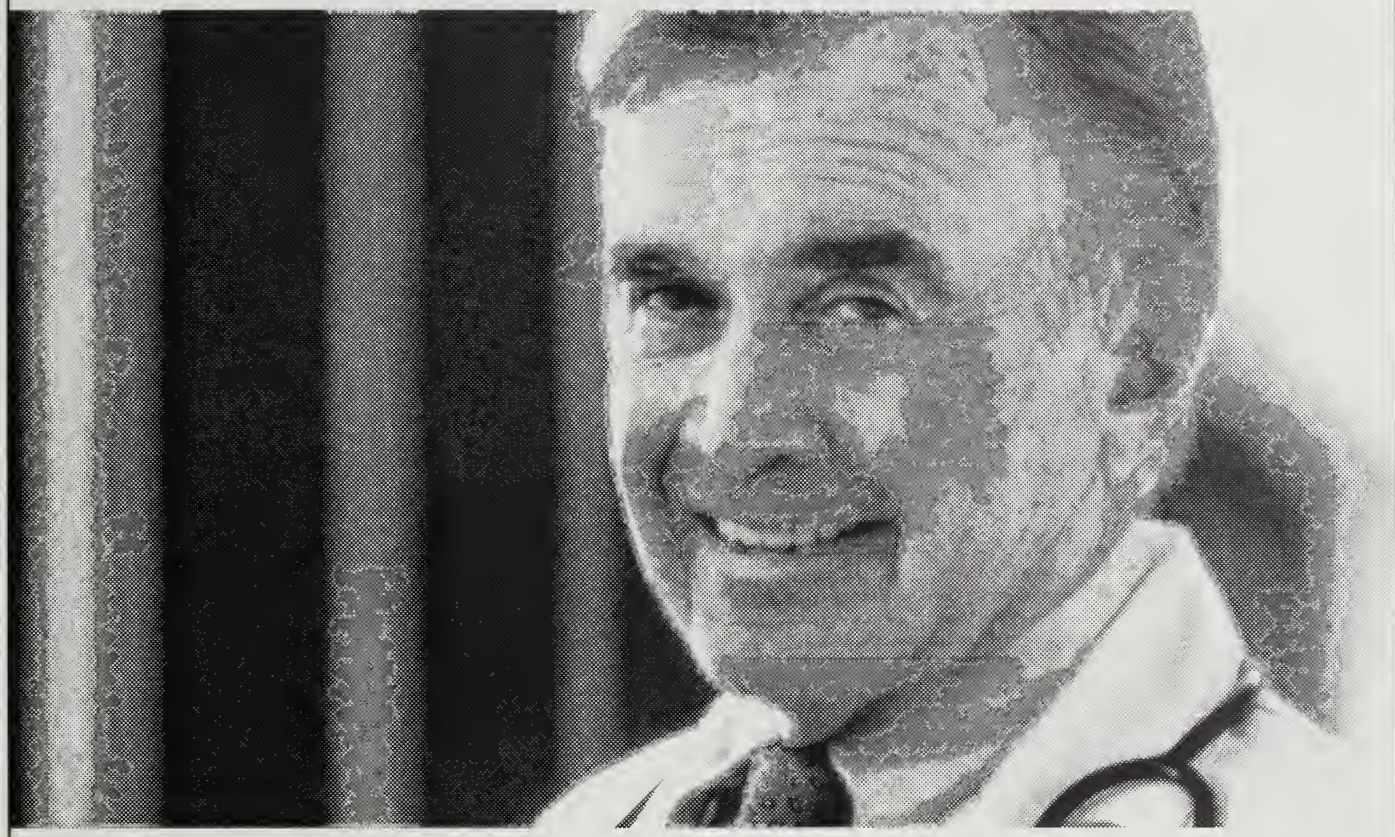
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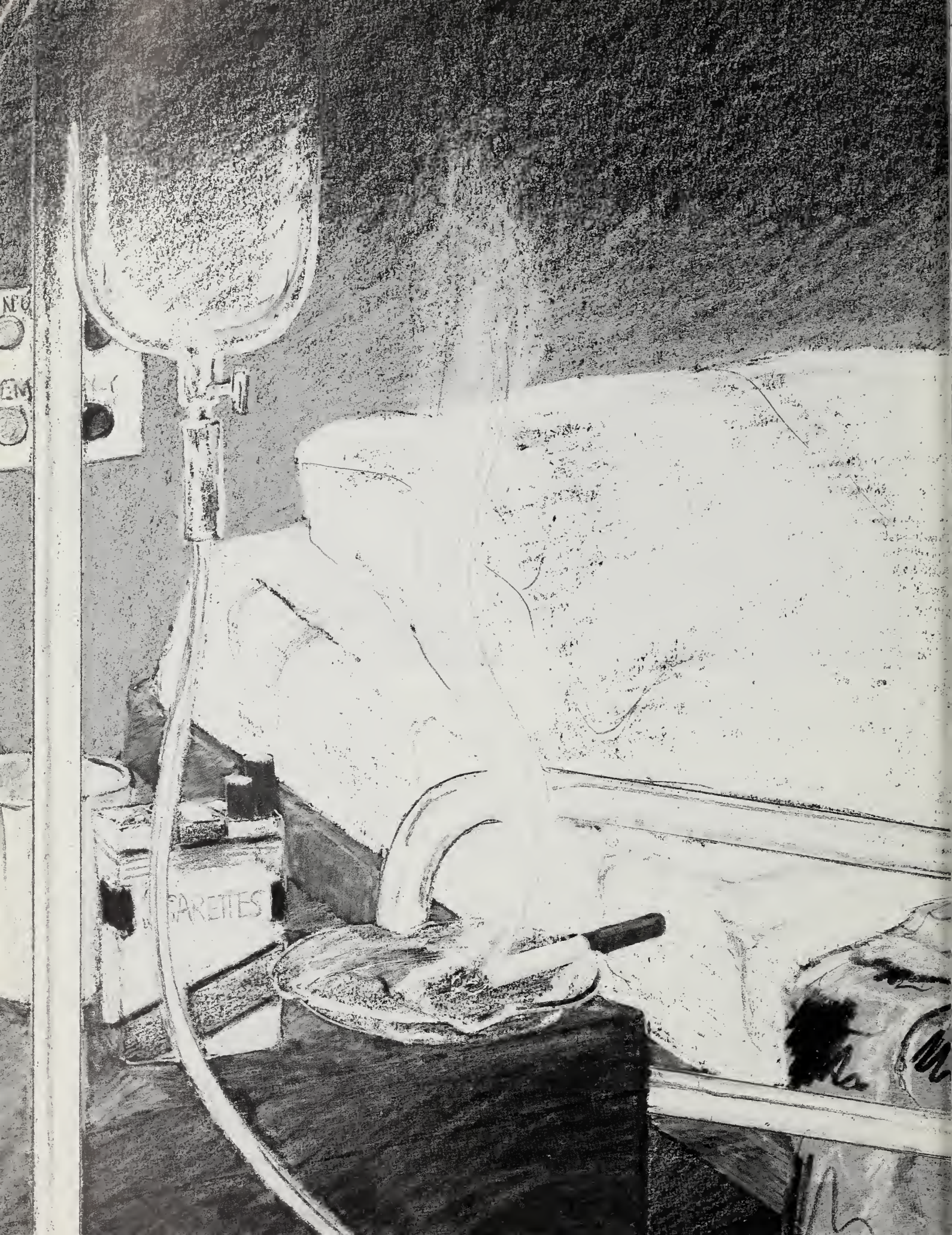
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The 1990/91 Kentucky Hospital Smoking Policy Survey: A Follow-Up

John Randall Thompson, MD; Christian Stauber, MD; Barbara Phillips, MD, MSPH, FCCP; Thomas C. Tucker, MPH

We surveyed all Kentucky hospitals regarding smoking policies iin 1989, 1990, and 1991. There were statistically significant increases in the numbers of hospitals which developed smoking policies and became smoke free between 1990 and 1991. The sale of tobacco in hospitals declined significantly between 1989 and 1991, as did the number of institutions providing smoking areas within the hospital. Survey respondents indicated that the JCAHO mandate prompted changes in smoking policies. Kentucky hospitals are leading the way in developing smoke-free environments, but externally imposed regulations have played a major role in promoting this progress.

Introduction

In 1989 the American Medical Association adopted Resolution 29 which advocated that all American hospitals ban tobacco use by January 1, 1991. Also, in its 1989 session, the Kentucky Medical Association endorsed Resolution J which called for smoke-free hospitals. We have previously reported the results of a 1989 survey which was designed to determine the smoking policy practices of Kentucky hospitals and to provide a baseline from which to measure the impact of AMA and KMA resolutions on smoke-free hospitals.[1]

The 1989 survey included 100% of the acute care hospitals in Kentucky. Of the 123 institutions surveyed at that time, nearly 90% had some type of smoking policy. However, only 6 of the hospitals were totally smoke free and 23 hospitals continued to sell tobacco products on the premises.

Attitudes and policies pertaining to the use and sale of tobacco are changing rapidly, even in Kentucky. The purpose of the present survey was to help measure the impact of the AMA and KMA resolutions and get some measure of interim change in smoking policies of Kentucky hospitals.

Methods

All acute care and psychiatric hospitals were identified through the 1988 and 1989 Kentucky Hospital Association Directory[2] and the Paired Community Laboratory System.[3] All identified institutions were sent standardized questionnaires. Hospitals not responding to the initial survey were contacted by telephone or a second mailed survey. Mail and telephone surveys were directed toward the institution's president, administrative director, or chief executive office. Through mail and telephone surveys, 100% of all Kentucky Hospitals participated in the survey for each of the 3 years.

Respondents to the survey were asked the following questions:

1. *Does your hospital have a smoking policy?* *YES_____ NO_____*

IF NO

a. *Is your hospital working on a smoking policy?* *YES_____ NO_____*
b. *What are the reasons most commonly given by administration or staff about not implementing such a policy?*

IF YES

a. *Please attach a copy of the smoking policy.*
b. *How long has that policy been in force?*
c. *Is your hospital "smoke-free"?* *YES_____ NO_____*
 (ie, does not allow smoking in the hospital under any circumstances)
d. *Are patients allowed to smoke in their rooms?*
 (circle one)
 1. *Yes*
 2. *Yes, with a doctor's order*

From the University of Kentucky College of Medicine (Drs Thompson, Stouber, and Phillips) and the University of Kentucky College of Allied Health (Dr Tucker), Lexington, Kentucky 40536-0084.
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Reprint requests to Division of Pulmonary and Critical Care Medicine, University of Kentucky, MN578 800 Rose St, Lexington, KY 40536-0084 (Dr Thompson).

3. *No*

e. *Is smoking limited to specific areas within the hospital?*
YES_____ NO_____

f. *Are smoking areas provided within the hospital for:*
— patients? YES_____ NO_____
— employees? YES_____ NO_____
— visitors? YES_____ NO_____

2. *Are tobacco products sold in your hospital? YES_____ NO_____*
3. *Please write any additional comments here:*

In 1991 hospitals were asked to respond to the following additional questions:

4. *Additional Questions:*
 a. *Are you aware of the AMA Resolution 29? YES_____ NO_____*
 (Calls for smoke-free hospitals by January 1, 1991)
 b. *Has enforcement of smoking regulations been a major obstacle in establishing or maintaining a smoking policy in your hospitals? YES_____ NO_____*
 c. *If your hospital is in a high tobacco-growing county, does/did this make it more difficult to establish, maintain or enforce a smoking policy?*
 YES_____ NO_____
 d. *If hospitals in your vicinity were smoke-free, would this make it easier for your hospital to develop/maintain a stricter smoking policy? YES_____ NO_____*
 e. *If JCAHO were to require all hospitals to be smoke-free, would your hospital have difficulty in establishing such a policy? YES_____ NO_____*

Data were collected and analyzed by computer using SuperStat[4] and the Paired Community Laboratory System.[3] Descriptive hospital data were obtained from the 1988 and 1990 Kentucky Hospital Association Directory.[2] The number of beds, number of admissions, average daily census, occupancy rate, average length of stay, and expenses per admission were calculated and compared using the paired T-test. Hospital ownership and available services (such as cardiac intensive care unit, open heart surgery facilities, cardiac catheterization, and hospice) were compared using the proportional Z test and Chi Square.

County demographics were obtained from the 1980 census data. County specific population, unemployment rate, poverty level, educational, and tobacco production rates were analyzed using the proportional Z test and Chi Square.

Appalachian counties were identified using the Appalachian Regional Commission's definition of the region. Metropolitan and non-metropolitan counties were identified using the US Census Bureau definition. Hospitals were considered "smoke free" if they prohibited smoking within their institutions except when explicitly ordered for a patient by a physician. Hospitals were considered to be "totally smoke free" if they prohibited smoking in their institution under any circumstances.

Results

One hundred seven, 123, and 122 hospitals were mailed questionnaires in 1989, 1990, and 1991, respectively. The majority of the institutions responded to the initial questionnaire with specific response rates of 75.7% in 1989, 69.1% in 1990, and 73.8% in 1991. Telephone follow-up of non-respondents resulted in a 100% response rate in all 3 years. In each of the 3 years, hospitals with established smoking policies were just as likely to respond to the survey as hospitals with no smoking policies. Likewise, there was no difference between the proportion of hospitals restricting tobacco use or selling tobacco and the likelihood of that hospital's returning the survey. The 1989 survey revealed that hospitals with cardiac intensive care units and cardiac catheterization facilities were more likely to respond to the survey ($p < 0.05$); however, this difference was not present in the 1990 and 1991 surveys.

Subsequent data analysis was performed only on non-psychiatric institutions. There were 112 non-psychiatric hospitals in 1989, 109 in 1990, and 108 in 1991. The survey data from each of these years is presented in Table 1. There was no statistically significant change in the number of hospitals reporting smoking policies between 1989 and 1990; however there was a significant increase ($p < 0.05$) between 1990 and 1991. Likewise, there was no significant change in the number of hospitals considered to be smoke free between 1989 and 1990, but there was a significant increase ($p < 0.01$) between 1990 and 1991.

In 1989 and 1990, 18 (16.1%) and 17 (15.6%) of the hospitals sold cigarettes. This number decreased to 8 (7.4%) between 1990 and 1991. The

decrease in the number of hospitals selling tobacco products between 1989 and 1991 was significant ($p < 0.05$).

In 1989, 80.4% of the hospitals provided smoking areas within the hospital. This percent decreased to 67.6% in 1991 ($p < 0.05$). There was also a statistically significant decrease ($p < 0.05$) in the number of hospitals allowing patients to smoke in their rooms during this same time period. There were significantly ($p < 0.05$) fewer hospitals providing smoking areas for patients, employees, and visitors in 1991 than in 1990.

In 1991, 92 (85.2%) of the respondents indicated that they were aware of AMA Resolution 29 which called for hospitals to ban tobacco use by January 1, 1991. Forty-eight (44.4%) of those surveyed indicated that the changes in their smoking policies were designed to meet the JCAHO mandate, which was to take effect on January 1, 1992.

Of the seven hospitals without smoking policies in 1991, six (85.7%) indicated that they were working on a policy to take effect in January 1992. These hospitals cited several problems with trying to develop and implement a smoking policy, including: "many hospital board members grew tobacco," "high percentage of employees and patients who smoked cigarettes," and "the counties' dependence upon tobacco growth for jobs and income." Other reasons included the perception that banning tobacco use in the hospital would "interfere with smokers' rights" and the concern of "offending patients and employees."

County social and economic factors were analyzed to determine their relationship to the likelihood of a hospital returning the survey, having a smoking policy, being smoke free, being totally smoke free, or selling tobacco products. In 1989 and 1990, hospitals from metropolitan areas were just as likely to return the survey as those from nonmetropolitan areas. However, in 1991, hospitals from metropolitan regions were more likely ($p < 0.01$) to return the survey. Likewise, metropolitan hospitals were just as likely to have a smoking policy as non-metropolitan hospitals in 1989, 1990, and 1991. However, there was a significant increase ($p < 0.05$) in the number of non-metropolitan hospitals with smoking policies between 1990 and 1991. There was a significant increase ($p < 0.01$) in the number of non-metropolitan hospitals that were smoke free between 1990 and 1991, but no significant difference between any of the 3 years and the likelihood of the hospital being totally smoke free or selling tobacco.

Table 1. All Non-Psychiatric Hospitals

	1989	1990	1991
Number of hospitals	112	109	108
Number with smoking policy	99 (88.4%)	92 (84.4%)	101 (93.5%)*
Number "smoke free"	10 (8.9%)	12 (11.0%)	32 (29.6%)*§
Number "totally smoke free"	6 (5.4%)	6 (5.5%)	8 (7.4%)§
Number who sell tobacco	18 (16.1%)	17 (15.6%)	8 (7.4%)
Number with smoking areas	90 (80.4%)	95 (87.2%)	73 (67.6%)*§
Number that allow patients to smoke in their rooms	57 (50.9%)	53 (48.6%)	37 (34.2%)*§
Number that provide patients with smoking areas	85 (84.8%)	82 (75.2%)	67 (62.0%)*§
Number that provide employees with smoking areas	95 (84.8%)	95 (87.2%)	67 (62.0%)*§
Number that provide visitors with smoking areas	95 (84.8%)	94 (86.2%)	63 (58.3%)*§

* Changes significantly different from 1990 $p \leq 0.05$.
§ Changes significantly different from 1989 ≤ 0.05.

In each year, hospitals in counties with high tobacco production were just as likely to return the survey as hospitals from counties with low tobacco production. There was a significant increase ($p < 0.01$) in the number of hospitals from counties with low tobacco production developing smoking policies and becoming smoke free between 1990 and 1991. Also, in 1991 hospitals from low-tobacco producing counties were more likely ($p < 0.05$) to be smoke free than hospitals from high-tobacco producing counties. However, no differences were seen in the number of hospitals that were totally smoke free or who sold tobacco products between counties with low and high tobacco production.

Hospitals from Appalachian counties were just as likely to return the surveys in all 3 years as hospitals from non-Appalachian counties. There was a significant increase ($p < 0.01$) in the number of non-Appalachian hospitals with smoking policies and who were smoke free between 1990 and 1991. Otherwise, Appalachian and non-Appalachian hospitals were just as likely to be smoke free, totally smoke free, and sell tobacco.

Hospitals from counties with a higher rate of poverty and hospitals from counties with higher unemployment rates were just as likely to return the questionnaire, have a smoking policy, be smoke free, or sell tobacco products as their counterparts. However, significantly more hospitals from counties with higher unemployment rates had smoking policies in 1991 than in 1990. In addition, there was a significant increase in the number of hospitals that were smoke free in

counties with lower unemployment rates between 1990 and 1991.

Hospitals from counties with lower educational rates were just as likely to return the survey, have a smoking policy, be smoke free, or sell tobacco products as hospitals from counties with higher educational rates. There was a significant increase in the number of hospitals from the better educated counties who had a policy ($p < 0.01$) and were smoke free ($p < 0.05$) between 1990 and 1991.

Discussion

In 1988, approximately 8,230 Kentuckians died of causes attributable to smoking, accounting for 22% of all deaths in the state.[5] Eight percent ($270 million) of the total cost for direct medical care in Kentucky in 1983 was attributable to cigarette smoking. Inclusion of the indirect cost would raise the total to $435 million.[6] The economic and health toll that tobacco takes on Kentucky is indeed high. As health care institutions, Kentucky hospitals have led the way in protecting and educating staff, patients, and visitors about the hazards of active and passive smoking. It is laudable that so many Kentucky hospitals elected to put smoking policies in place prior to their being mandated by the Joint Commission of Accreditation of Health Organizations.[7] Presumably, after this mandate goes into effect January 1, 1992, 100% of Kentucky hospitals will prohibit smoking unless authorized by physician prescription for an individual patient. The current report indicates that many health care institutions will take the initiative and assume the responsibility for the health, education, and safety of their patients, employees, and visitors. However, the fact that only a minority of the hospitals (29.6%) were smoke free in the 1991 survey (7 months after the AMA Resolution 29 target date), suggests that the national mandate was necessary, particularly in Kentucky.

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Primary Thrombosis in the Upper Extremity

David S. Overstreet, MD; William H. Skinner, MD; Thomas M. Roy, MD

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Deep vein thrombosis may occur in the axillary or subclavian veins in the upper extremities, sometimes in young patients without the typical risk factors for thrombus development. This unusual clinical situation usually follows strenuous activity and is often referred to as "effort" thrombosis. Since some cases have occurred with mild exertion and there is a lack of obvious predisposing vessel trauma, a more correct term might be "primary" thrombosis. Early recognition of this condition is necessary to prevent potentially fatal acute effects and minimize chronic sequelae.

Introduction

Thrombosis of the axillary or subclavian veins of the upper extremity without an apparent identifiable cause accounts for approximately 2% of all deep vein thromboses.[1] Its occurrence is sometimes referred to as Paget-Schroetter's syndrome in honor of two physicians who described this problem over a decade ago.[2] The population at risk includes young, active, and otherwise healthy individuals who engage in unusual physical exertion or overuse of an upper extremity common to athletic pursuits or manual labor.

Due to the sporadic occurrence of this event, controversy persists about its pathogenesis, diagnosis, and treatment. We describe a patient who experienced primary thrombosis of the right upper extremity and provide a review of current concepts regarding this clinical entity.

Case Report

The patient is a 39-year-old male who presented to the Louisville Veterans Administration Hospital emergency department with right upper extremity swelling. He was otherwise healthy and had not required previous medical attention. Approximately 2 days prior to his presentation, he had started a weight lifting regimen. Within 24 hours of starting this activity he noted mild swelling involving both the proximal and distal portions of the right arm. Initially he experienced no discomfort, tenderness, or decrease in motor strength. With increased swelling, however, he developed a tingling and itching sensation in this extremity. Range of motion was decreasing with the increasing edema.

He denied dyspnea, cough, and chest pain. His review of systems was unremarkable except for a single episode of Meniere's disease 1 year earlier. The patient did not use alcohol or tobacco. His family history was unremarkable.

He was in no cardiorespiratory distress and his vital signs were normal. Examination of the heart and lungs was normal. There was a 5 cm difference in the circumference of the right upper extremity when compared to similar sites on the left extremity. All compartments were soft and nontender. Range of motion at the elbow was mildly limited. All pulses were present and normal.

The patient's laboratory work was all normal including clotting parameters and hemogram. The erythrocyte sedimentation rate was slightly increased. Chest radiograph and electrocardiogram were normal.

Unilateral deep vein thrombosis of the upper extremity was suspected and subsequently confirmed by venography which demonstrated a complete thrombosis of his subclavian vein (Fig 1). His axillary, cephalic, and basilic veins remained patent (Fig 2). The patient was anticoagulated with intravenous heparin and a therapeutic PTT was maintained by continuous infusion. The diagnosis of primary or "effort" thrombosis was confirmed when further evaluation by computerized tomography of the neck, shoulder, chest, and abdomen failed to reveal any comorbid disease or mechanical cause for his thrombosis. Coumadin was started and continued after a proper course of heparin. The patient demonstrated full

resolution of edema after 1 week. He was started on shoulder strengthening exercises 3 weeks after admission. He completed 3 months of Coumadin and has not experienced chronic residual symptoms.

Discussion

Venous thrombosis of the upper extremity is conventionally categorized as primary or secondary thrombosis.[2] The latter condition occurs more frequently and is more familiar to most clinicians. It occurs in conjunction with an evident disease process, the use of central venous catheters, carcinomatous compression, or direct trauma to the vein or extremity. On the other hand, primary thrombosis occurs in otherwise healthy individuals in the absence of an immediately apparent cause. Because many of the individuals are young, healthy, and active individuals with muscular builds and athletic pursuits, primary venous occlusion is often initially overlooked as a cause of upper extremity discomfort.

One or more of the tenets of Virchow's triad must be operative in the pathogenesis of primary thrombosis of the upper extremity. Explanations for this event necessarily focus on the presence of circulatory stasis, vessel wall injury, or hypercoagulability of the blood.

Many investigators presume that circulatory stasis is the major contributing factor. Most primary thrombi are found in that portion of the subclavian vein that transverses the narrowed space between the clavicle and the first rib. Circulatory stasis is attributed to abnormal anatomic structure of the thoracic outlet which extrinsically compresses the vessel.[3] If one accepts this explanation, then thoracic outlet surgery should be a reasonable intervention that would prevent or relieve circulatory stasis.[4] Unfortunately, a consistent relationship between primary thrombosis and extrinsic compression of the vein at the thoracic outlet cannot be demonstrated angiographically.

In lieu of demonstrable obstruction at the thoracic outlet, it has been hypothesized that intimal injury to the vascular endothelium may occur during overuse of the upper extremity. Anatomical studies demonstrate that maneuvers which require repeated adduction and external rotation of the shoulder move the clavicle onto the first rib and provide the potential for compression injury of the vein. During strenuous and repetitive activities, adduction of the shoulder may be fol-



Fig 1 — Digital enhancement imaging of the venogram of the right upper extremity showing obstruction of venous return.



Fig 2 — Focused assessment of the thrombus which occludes the proximal subclavian vein. Collateral circulation is patent and visible above the obstruction.

lowed by hyperabduction with stretching of the vessel. A tear in the intima of the vascular endothelium may then act as a nidus for thrombus formation and lead to vessel occlusion.[1]

The third component of Virchow's triad to be considered is hypercoagulability. Interestingly, this syndrome occurs primarily in young men. Notable exceptions have involved female athletes who also used oral contraceptives which may affect coagulability by decreasing antithrombin III activity.[5] For the most part, mechanical factors rather than hypercoagulability are responsible for this syndrome.

The young individual typically presents with the triad of aching pain, nonpitting edema, and mottled cyanosis of the entire upper extremity. Each of these features may occur abruptly or gradually, usually within 24 hours of some unaccustomed or repetitive motion. Additional subjective complaints include weakness, heaviness, or tingling in the involved extremity. Only one-third of affected individuals have a palpable or tender vein.[6] Symptoms of dyspnea, tachypnea, chest discomfort, and cough should suggest pulmonary thromboembolism. There is a 12% incidence of clinically overt distal embolism associated with primary thrombosis of the upper extremity.[7] Fatal embolism from this source is unusual.[8]

When primary thrombosis is suspected, doppler ultrasound has been proposed as a noninvasive method for initial diagnosis and long-term follow-up.[9] While this modality obviates the risk of reaction to contrast material, clot displacement, and resultant phlebitis, its accuracy is exquisitely dependent on operator experience. Its role in directing diagnosis and treatment of primary thrombosis will likely expand as technology improves.[10] It has not replaced venography as the diagnostic procedure of choice.

Definitive diagnosis has traditionally involved invasive phlebographic studies with contrast imaging. This procedure can establish the presence and extent of the occlusion. It will also identify the presence of any collateral circulation which impacts on the patient's eventual prognosis. The patients with adequate collaterals suffer fewer chronic sequelae. The additional information is essential to insure selection of the most suitable treatment. The therapeutic options include thrombectomy, surgical decompression, thrombolytic therapy, or conventional heparin anticoagulation.

Surgical therapy may be considered when evidence of thoracic outlet abnormalities are confirmed, especially if additional symptoms suggest concomitant or earlier neurological symptoms. Embolectomy with transaxillary first rib resection may be proposed. It has been argued that surgical intervention is important to avoid permanent occlusion because recanalization of veins in the upper extremity is less likely than in the lower extremity.[11] This aggressive attitude has largely been tempered by the observation that most individuals with thoracic outlet syndrome have sustained chronic intermittent vessel compression and have developed an extensive functional collateral circulation. The collateral vascular bed will continue to function in the event of permanent vessel scarring and fibrosis at the site of the primary thrombosis. Since first rib resection does not benefit the collateral circulation, surgery should generally be reserved for those patients with additional neurological symptoms involving the brachial plexus or those patients without sufficient collaterals.

Thrombolytic therapy is a relatively safe intervention in this young and otherwise healthy population. It has been very successful in effecting complete or partial resolution of primary thrombosis. Its success is dependent on a rapid diagnosis and the age of the thrombus. If administered within 72 hours of the onset of symptoms, 94% of primary thromboses resolve.[12] Efficacy drops dramatically after this interval. The presence of an extensive collateral network of veins bypassing an axillary or subclavian thrombus should suggest to the clinician that the thrombus has been developing gradually or that an anatomic narrowing is present that will predispose to another thrombus. In this context, the cost-risk-benefit ratio of thrombolytic therapy should be carefully reconsidered.

If collateral circulation allows venous return to the heart, conservative treatment with heparin anticoagulation and arm rest is the mainstay of therapy.[13] Heparin therapy should stabilize the primary thrombosis and decrease the incidence of pulmonary embolism during the acute event. Long term use of Coumadin following anticoagulation with heparin is controversial. No clinical prospective randomized comparisons of treatment have been carried out. Retrospective analyses suggest that if collateral circulation is evident on venogram, long term outcome from conservative therapy is comparable to more aggressive approaches.

In the absence of collateral circulation, immediate definitive treatment with surgery or

thrombolytic agents renders greater long term success and less chronic sequelae. While most patients return to normal function and activity, about 60% will have mild residual discomfort in the affected extremity when strenuous exertion is necessary. A minority of patients will experience chronic weakness and heaviness in the extremity which is generally the dominate limb.[1, 13]

In summary, the natural history of primary thrombosis of the upper extremity is still being defined. Optimal management is controversial and must be individualized according to the presence of thoracic outlet abnormalities and/or sufficient venous collateral networks.

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The Pulmonary Autograft for Aortic Valve Replacement in the Young

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Until recently, a mechanical prosthesis has been the substitute valve of choice for children and young adults who require aortic valve replacement. The preference for using mechanical valves in this group resulted from the discovery that porcine valves experienced accelerated structural degeneration in the young. Unfortunately, mechanical valves impose a constant risk of thromboembolism, resulting in a lifelong requirement for anticoagulant therapy. Thus, young patients with the potential for longer survival face a higher likelihood of having a thromboembolic or hemorrhagic event. To provide young patients with a durable replacement aortic valve that is not thrombogenic and does not require anticoagulation, some cardiac surgeons are transferring the patient's own pulmonary valve to the aortic position and replacing the pulmonary valve with a cryopreserved valve (a homograft) from a cadaveric donor. Long-term follow-up of the experience of Mr Donald Ross of London, England, who introduced this operation in 1967, indicates that the pulmonary autograft has the best event-free survival of any form of aortic valve replacement. The technical demands of this operation are greater than those for routine aortic valve replacement with a mechanical prosthesis; however, the pulmonary autograft can be performed at an acceptably low risk. As more experience is acquired with this technique, it may become the preferred procedure for aortic valve replacement in the young.

Introduction

When aortic valve replacement becomes necessary, the surgeon and cardiologist must decide upon the best substitute valve for each patient. Since there is no perfect valve prosthesis, the choice is most commonly between a mechanical or a porcine valve. It has been demonstrated that both types of valves perform satisfactorily, but each has a major disadvantage. The mechanical valve has a tendency to form thrombi, and the porcine valve has a tendency to wear out. Thus, patients with mechanical valves must accept a lifelong regimen of anticoagulation, while patients with porcine valves must anticipate reoperation sometime in the future. The recognition of the limited durability of the porcine valve has, in recent years, confined its use to elderly patients or to patients with clear-cut contraindications to anticoagulation. The thromboembolic risk and the anticoagulation requirement imposed by a mechanical valve may be acceptable for patients over 50 years of age. However, for younger patients, especially children and teenagers, a mechanical valve imposes many years of thromboembolic and hemorrhagic risk. Moreover, should the patient be a young female, the requirement for anticoagulation therapy precludes her from bearing children.

In recent years, the shortcomings of both mechanical and porcine valves have encouraged some surgeons to investigate a relatively complex but nevertheless conceptually appealing procedure called the pulmonary autograft. In this procedure, the patient's normal pulmonary valve is removed and transferred to the site of the diseased aortic valve. The void left at the site of the pulmonary valve is then filled with a cryopreserved valve obtained from a cadaver (a homograft, also referred to as an allograft). Theoretically, the advantage of this technique is that it replaces the abnormal aortic valve with a valve that has the exact anatomical configuration of a normal aortic valve, which has not been subjected to any preservation process, and is in no way immunologically foreign to the patient. The homograft valve inserted in the pulmonary position may experience some deterioration over time, but the hydraulic factors of the pulmonary circulation subject the homograft to less stress than it would sustain in the systemic circulation. Additionally, dysfunction of the pulmonary valve is far better tolerated than dysfunction of the aor-

tic valve. Furthermore, should reoperation become necessary to replace the homograft, re-replacement can be performed with greater ease and with lower risk than re-replacement of the aortic valve.

History of the Pulmonary Autograft

The pulmonary autograft is not a new technique. The idea of autotransplantation of the pulmonary valve to another site in the heart was first described and performed experimentally in 1961 by Drs Lower, Stofer, and Shumway at Stanford University.[1] Experimental replacement of the aortic valve with a pulmonary autograft was reported by Pillsbury and Shumway in 1966.[2] Mr Donald Ross, in London, England, first performed the procedure clinically in 1967,[3] 5 years after being the first surgeon to replace an aortic valve with an aortic homograft.[4] By 1967, Mr Ross recognized signs of degeneration in some of the homograft valves he had implanted. The pulmonary autograft operation, often referred to as the Ross "Switch" Procedure, was a bold venture in the early history of open heart surgery.[3] At that time, few other surgeons were willing to attempt so complex a procedure when valve prostheses, which were relatively simple to implant, were available.

The mechanical valve, introduced in 1960, was technically easier for the surgeon to insert than the aortic homograft, which required a freehand technique. Furthermore, homograft valves were limited in availability and had a refrigerated shelf life of less than 2 weeks. The thromboembolic complications of mechanical valves, however, could not be ignored and the desire to improve the availability of tissue valves led to the development of the glutaraldehyde preserved and stent mounted porcine valve. In the 1970s, if there was any concern about thromboembolism or anticoagulation, a porcine valve was the valve of choice. In fact, at one time it was considered the ideal valve replacement for children.[5] By the 1980s, however, the limited durability of the porcine valve became evident. The rate of porcine valve degeneration was especially high in children and young adults.[6] Recognizing the limited durability of the porcine valve, some surgeons began reexamining the results of the aortic homograft. Since aortic valve replacement using homograft valves had never achieved popularity with cardiovascular surgeons, only a few series were available for evaluation.[7-9] However, these series suggested that aortic homografts were more resistant to degeneration than porcine valves. The incidence of endocarditis was low, and thromboembolic events were rare. Furthermore, reports of techniques to preserve aortic homografts indicated that the newer process of cryopreservation maintained tissue viability, extended shelf life indefinitely, and prolonged homograft valve survival after implantation.[10]

The increased availability that cyropreservation provided and the evidence that homograft durability may be improved with this technique peaked the interests of many surgeons dissatisfied with porcine valves but still concerned about the thromboembolic and hemorrhagic complications of the mechanical valve. The worldwide increase in all forms of tissue and organ transplantation also resulted in the greater availability of homograft heart valves. Most organ procurement agencies will routinely harvest these valves if the heart as a whole is unsuitable for transplantation. A number of regional tissue cryopreservation agencies as well as one nationwide enterprise (CyroLife, Marietta, GA) currently employ this technology to preserve many types of human tissue, including heart valves, making them available to institutions that have clinical use for them. Assuming adequate procurement of donor tissue, any institution active in homograft valve implantation can maintain a supply of homografts of various sizes in a liquid nitrogen freezer. When a patient is in need of one, a valve of the appropriate size can be easily thawed and implanted.

Immunosuppressive medication has not been required for most patients receiving homograft valves. Furthermore, since the supply of these valves is limited, matching of blood and tissue type is not routinely performed. In spite of the absence of immunosuppressive therapy and blood and tissue matching, acute rejection of homograft valves has been extremely rare. The reason for this low immunogenicity is not known, but it may be related to a decreased antigenic expression and a high ratio of collagen to viable cellular matrix in the homograft valves.

Heart surgeons have found homografts particularly useful for reestablishing right ventricle to pulmonary artery continuity in patients with congenital heart defects that lack this connection, since its ease of insertion and durability in this position are significantly better than any known alternative. In the aortic position, however, the technical demands of freehand implantation, along with its very modest improvement in dura-

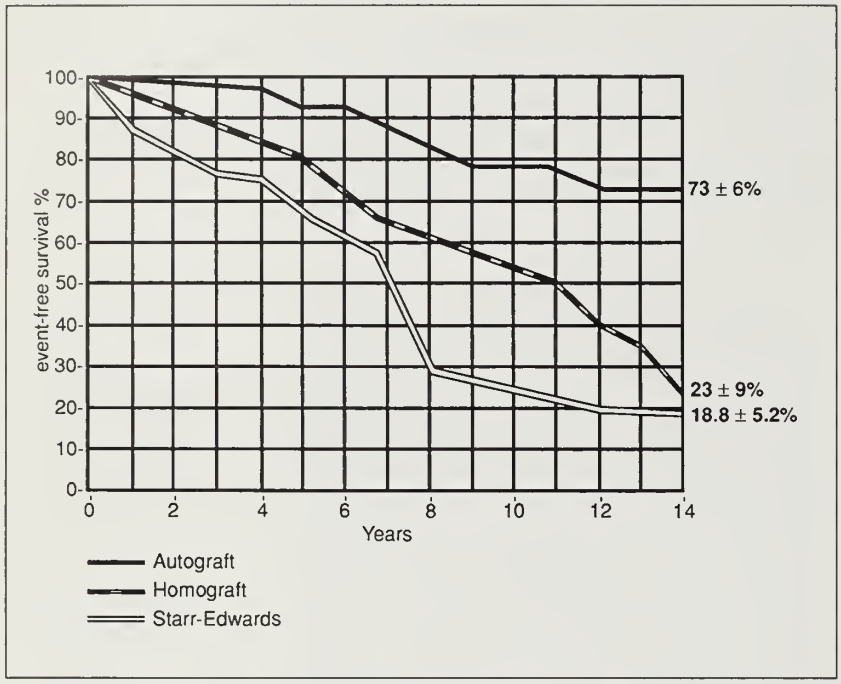


Fig 1 — Comparison of actuarial event-free survival in three groups of patients undergoing aortic valve replacement at the National Heart Hospital in London, England. Survival without event (such as thromboembolism or reoperation) was superior in patients with pulmonary autografts compared to those with aortic homografts or Starr-Edwards ball valves. (Modified with permission from Robles A, Vaughan M, Lau JK, Bodnar E. Long term assessment of aortic valve replacement with autologous pulmonary valve. Ann Thorac Surg *1985;39:242.)*

bility over a porcine valve, have discouraged many surgeons from using a homograft for routine aortic valve replacement. There are, however, some very specific instances in aortic valve surgery when a homograft valve may be the valve of choice. They include patients with active endocarditis of the native or prosthetic aortic valve, and those with major contraindications to anticoagulation. Recognizing that homograft replacement has a role, albeit limited, in heart surgery, some surgeons feel that the long-term results of homografts for aortic valve replacement could be improved by applying Mr Ross' concept of the pulmonary autograft to selected patients.

The Ross Data

Long-term evaluation of the pulmonary autograft for aortic valve replacement is available, but unfortunately is essentially limited to the experience of one surgeon, Donald Ross. In a 1988 report of the pulmonary autograft experience of Mr Ross, Matsuki et al[11] reported on 241 patients operated on between 1967 and 1986. The majority of patients were between 20 and 30 years of age (range, 9 to 60 years). This study provided a total of 1,130 patients-years of follow-up; the longest follow-up was 18 years and 7 months. The overall 30-day mortality in this series was 6.6% (16 patients), but there were no deaths within 30 days of surgery after 1976. In the follow-up there were only 19 late deaths, with an actuarial survival rate of 57.3% ± 9.6% at 19 years. None of the patients in this study received anticoagulation therapy and no episode of thromboembolism was reported. Reoperation was necessary in 48 patients. Twelve of the reoperations (25%) were to repair or replace the valve or tissue used to reconstruct the right ventricular outflow tract. These 12 patients were most commonly those who, early in the series, had received an autologous fascia lata valved conduit. Of the patients requiring reoperation on the pulmonary autograft, 7 had bacterial endocarditis and 24 were technical failures relating to problems with the freehand insertion technique. Within the entire series only one patient required reoperation because of primary degeneration of the autograft valve. Most reoperations were encountered in the first half of the series when there was less experience with the implant technique and when autologous fascia lata valved conduits were used to replace the pulmonary valves. The actuarial results presented in this report[11] are superior to that for any other valve prosthesis. In a prior publication, Robles and associates[12] had compared the pulmonary autograft experience of Mr Ross with the long-term results they had with Starr-Edwards aortic valves, and with homografts for aortic valve replacement (Fig 1). At 14 years of follow-up, 73% of the pulmonary autograft patients were free of valve-related events, whereas only 23% of homograft patients and 18.8% of patients receiving Starr-Edwards valves did not have a valve-related death or other valve-related complication.[12] The only other study reporting long-term results of the pulmonary autograft is that of Gonzalez-Lavin et al,[13] who operated on 12 patients between 1967 and 1971. There was only one hospital death (8.3%). Actuarial survival in the overall group was 66% at 16 years, with no reoperation for degeneration of the autograft, and only one reoperation for malfunction of the homograft in the right ventricular outflow tract. One patient required reoperation at 15 months, secondary to technical malalignment of the autograft, and one required reoperation at 13

½ years because of endocarditis. It is unfortunate that these two series are the only long-term studies reporting on this technique. However, both studies corroborate the structural durability of the pulmonary autograft in the aortic position. Furthermore, the only valve-related events that occurred were related to infection or technical factors. The incidence of infection in both studies was similar to the low level seen in homograft series, and the technical problems appeared to diminish with increasing experience of the surgical team.

Despite the clinical evidence of its durability and freedom from thromboembolism, pulmonary autograft replacement of the aortic valve was shunned by virtually all cardiovascular surgeons other than Mr Ross, until Dr Ronald Elkins and his associates at the University of Oklahoma began their clinical series in 1986.[14] That series now exceeds 75 patients with an overall mortality rate of 6.7%. The experience of Elkins and his associates is particularly noteworthy because they applied this technique to children as young as 2 years of age. Their preliminary data suggests that unlike any other substitute valve, a pulmonary autograft in a small child will grow.[15] Now with the encouraging results from Elkin's group added to the Ross data,[16] more surgeons are beginning to employ this technique in selected patients (Personal communications with Kouchoukos NT, St Louis, MO, and David TE, Toronto, Ontario).

The Experience at Louisville

Our experience with the pulmonary autograft began in the fall of 1990 at two of the University of Louisville's affiliated hospitals (Kosair Children's Hospital and Norton's Hospital). We have used the technique with success, and without a mortality, in six carefully selected patients ranging in age from 9 to 40 years. Case studies of two of these patients follow.

Case 1

A 9-year-old boy was born with aortic stenosis and coarctation of the aorta. He underwent repair of the coarctation at 3 months of age and within the next 6 months underwent open aortic valvotomy. Since then he had been asymptomatic, but an increase in intensity of his heart murmur, and electrocardiographic evidence of increasing left ventricular hypertrophy, prompted reevaluation. Cardiac catheterization demonstrated complex left ventricular outflow tract obstruction with stenoses below the valve, at the level of the valve and above the valve. The total gradient from left ventricular apex to ascending aorta was 100 mm Hg. In view of the multiple levels of stenosis, the high grade of left ventricular outflow tract obstruction, and the presence of moderate-to-severe aortic insufficiency, it was believed that the child was a candidate for aortic valve replacement as well as for opening up all three levels of stenosis. At operation, the complexity of the left ventricular outflow tract obstruction was evident. There was marked narrowing of the aorta at the level of the commissures, consistent with supra-aortic stenosis. The valve itself was bicuspid, stenotic, and insufficient. Beneath the valve there was both membranous and muscular outflow tract obstruction. At this point it was decided to combine the pulmonary autograft technique with a ventricular septoplasty (Konno procedure).[17] The combination of these two techniques would replace the aortic valve and eliminate all levels of left ventricular outflow tract obstruction.

The patient came off cardiopulmonary bypass without difficulty and without a measurable gradient between the left ventricle and the aorta. On the 7th postoperative day the patient was discharged, without the need for anticoagulants. Since discharge, the patient has done well. Follow-up color Doppler echocardiography performed at 1 and 2 years has shown only trivial neoaortic insufficiency, and no evidence of residual left ventricular outflow tract obstruction.

Case 2

This 40-year-old woman had been followed since early childhood for a combination of defects including aortic stenosis, aortic insufficiency, infundibular stenosis, and a small ventricular septal defect. The patient had been clinically well-compensated until the past few years when she began to notice a significant decrease in her tolerance for exercise. Cardiac catheterization was performed, which revealed moderate aortic insufficiency as well as an aortic gradient of over 70 mm Hg. In addition, there was a 40 mm gradient across the infundibulum, as well as a small ventricular septal defect. She was believed to be a candidate for aortic valve replacement as well as resection of her infundibular stenosis and ventricular septal defect closure. The options of mechanical, porcine, homograft, and pulmonary autograft aortic valve replacement were fully discussed with the patient and her physician husband. Because of concerns of the thromboembolic risk of a mechanical valve as well as the

desire to preserve her reproductive potential, she desired to have her valve replaced with the tissue valve that offered the greatest potential for durability — the pulmonary autograft. At the time of surgery she was found to have an insufficient aortic valve and membranous subaortic stenosis in addition to the predicted infundibular stenosis and ventricular septal defect. Through the right ventriculotomy that was created by the harvest of the pulmonary autograft, the infundibular stenosis was easily resected and her ventricular septal defect closed. The subaortic stenosis was resected and the aortic valve and root were replaced by the pulmonary autograft. The patient was discharged 1 week after surgery, without the need for anticoagulants. Physical examination on her first postoperative visit 6 weeks after surgery revealed a completely normal cardiac examination without evidence of cardiac murmur. Within 2 months after surgery she was able to return to full-time work.

The Technique

The pulmonary autograft concept is straightforward, but the technical aspects of the procedure are more complex than for routine aortic valve replacement using a standard prosthesis. Surgeons with experience with aortic homografts should achieve success with the pulmonary autograft. Figure 2 A-D demonstrates the root replacement technique using a pulmonary autograft. After initiation of cardiopulmonary bypass and cardioplegic arrest of the heart, the pulmonary artery is opened just proximal to the bifurcation of the pulmonary arteries and the pulmonary valve is visualized. If the valve appears normal, the pulmonary artery is divided at this point and an incision is made in the infundibulum several millimeters proximal to the pulmonary valve. This cylinder, which includes the pulmonary valve, the main pulmonary artery and a rim of infundibular muscle, is carefully dissected free, taking care not to injure the left anterior descending coronary artery or the first septal perforator (Fig 2A). This autograft root is measured with a Hegar dilator or valve sizer and a cyropreserved pulmonary homograft of similar size is obtained and thawed. With the root replacement technique, the native aorta is opened and most of the aortic root is excised down to the native annulus (Fig 2B). This gives excellent exposure of the left ventricular outflow tract, and if an annular enlargement technique is indicated (such as in Case 1) it is performed at this time. Both the right and left coronary artery ostia are carefully preserved as 4-5 mm buttons (Fig 2B). The pulmonary autograft, oriented in such a way that its valve commissures match those of the replaced aortic valve, is then sewn to the left ventricular outflow tract with running polypropylene sutures (Fig 2C). For small children a polydioxane suture is used. Openings are then made at the appropriate positions in the sinuses of the autograft root to permit reimplantation of the two coronary arteries. Anastomosis is then performed between the autograft and the distal aorta (Fig 2C). The thawed pulmonary homograft is then inserted in the orthotopic position and secured with running polypropylene sutures (Fig 2D).

The pulmonary autograft can also be performed with the native aorta left intact, with the pulmonary valve sewn freehand inside it. This technique may diminish the risk of hemorrhage or myocardial ischemia from coronary malposition which are potential problems of the root replacement technique. The freehand technique, however, generally requires a close match in size between the pulmonary and aortic valves. In our experience, such a match has been unusual. Furthermore, the data in the reports cited above indicate that the majority of problems with the pulmonary autograft were related to the technical aspects of suspending the pulmonary valve inside the aorta.[11, 13] Thus, since the root replacement technique can be used in virtually all situations, can be performed expeditiously, and maintains the geometric configuration of the original trileaflet valve without distortion, it is currently the technique we prefer.

Patient Selection

The pulmonary autograft is not the procedure of choice for all patients who require aortic valve replacement. The potential advantages of the technique must be weighed against its increased complexity. Although the operative mortality that has been reported for the pulmonary autograft is low, it will always be higher than that for simple aortic valve replacement with either a mechanical or porcine prosthesis. The increased complexity of the pulmonary autograft adds significantly to the duration of aortic cross clamping and to the potential for hemorrhage or technical error. Thus, in most cases the pulmonary autograft should be reserved for patients less than 50 years of age. The younger the patient, the greater is the

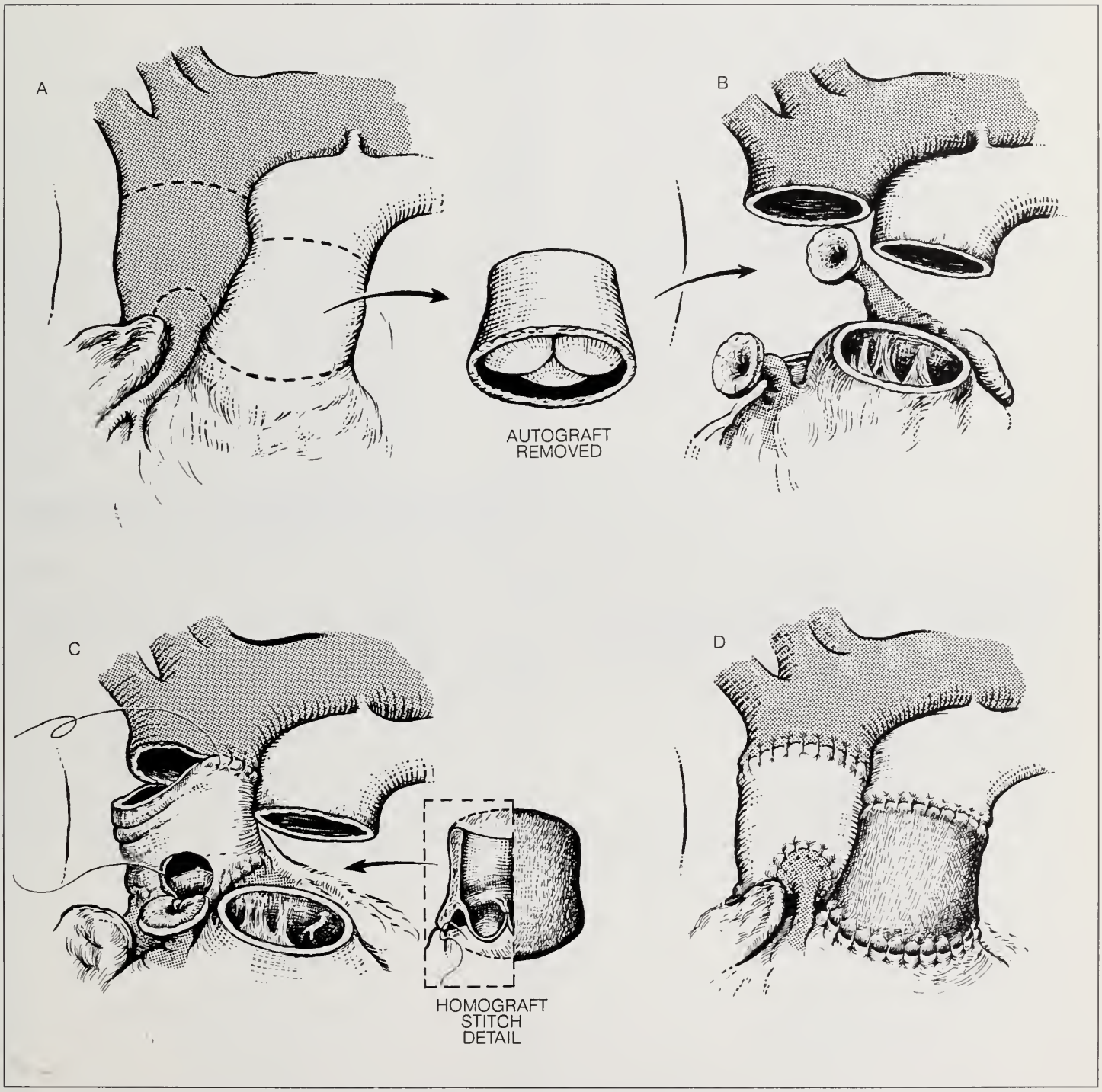


Fig 2 — The root replacement technique for aortic valve replacement with an autologous pulmonary valve. (A) The pulmonary valve, main pulmonary artery, and a rim of infundibular muscle are removed as a cylinder. (B) The native aortic root is excised down to the annulus of the aortic valve and the valve leaflets are removed. The coronary artery ostia are preserved as buttons. (C) The valve commissures of the pulmonary autograft root are oriented to match those of the removed aortic valve and the autograft root is sewn in place. The two coronary buttons are reimplanted in appropriate positions in the sinuses of the autograft root. (D) A thawed cryopreserved pulmonary homograft is inserted in the orthotopic position. The shaded vessel represents the aorta, the vessel without shading is the pulmonary artery, and the stippled area is the cyropreserved homograft.

advantage of the autograft technique. The potential for growth of the autograft may make this procedure especially useful for the small child requiring aortic valve replacement. It must be noted, however, that the homograft placed in the pulmonary position will not grow. Subsequent reoperation on the right ventricular outflow tract is likely in those children receiving homografts smaller than 18 mm in diameter. The young woman in need of aortic valve replacement, who is committed to having her own family, is probably the most ideal candidate for the pulmonary autograft procedure. However, no matter the sex or age, the pulmonary autograft should not be used in those patients with marginal ventricular function. In such patients, priority must be given to a functional but expeditious operation.

Summary

Dissatisfaction with valve prostheses currently available for use in young patients has renewed interest in the pulmonary autograft technique for aortic valve replacement. Long-term follow-up of the experience of Donald Ross suggests that the pulmonary autograft may provide the best event-free survival of any technique for aortic valve replacement. The procedure is technically more challenging than routine aortic valve replacement, but when performed carefully in appropriately selected patients, it can be performed with low mortality.

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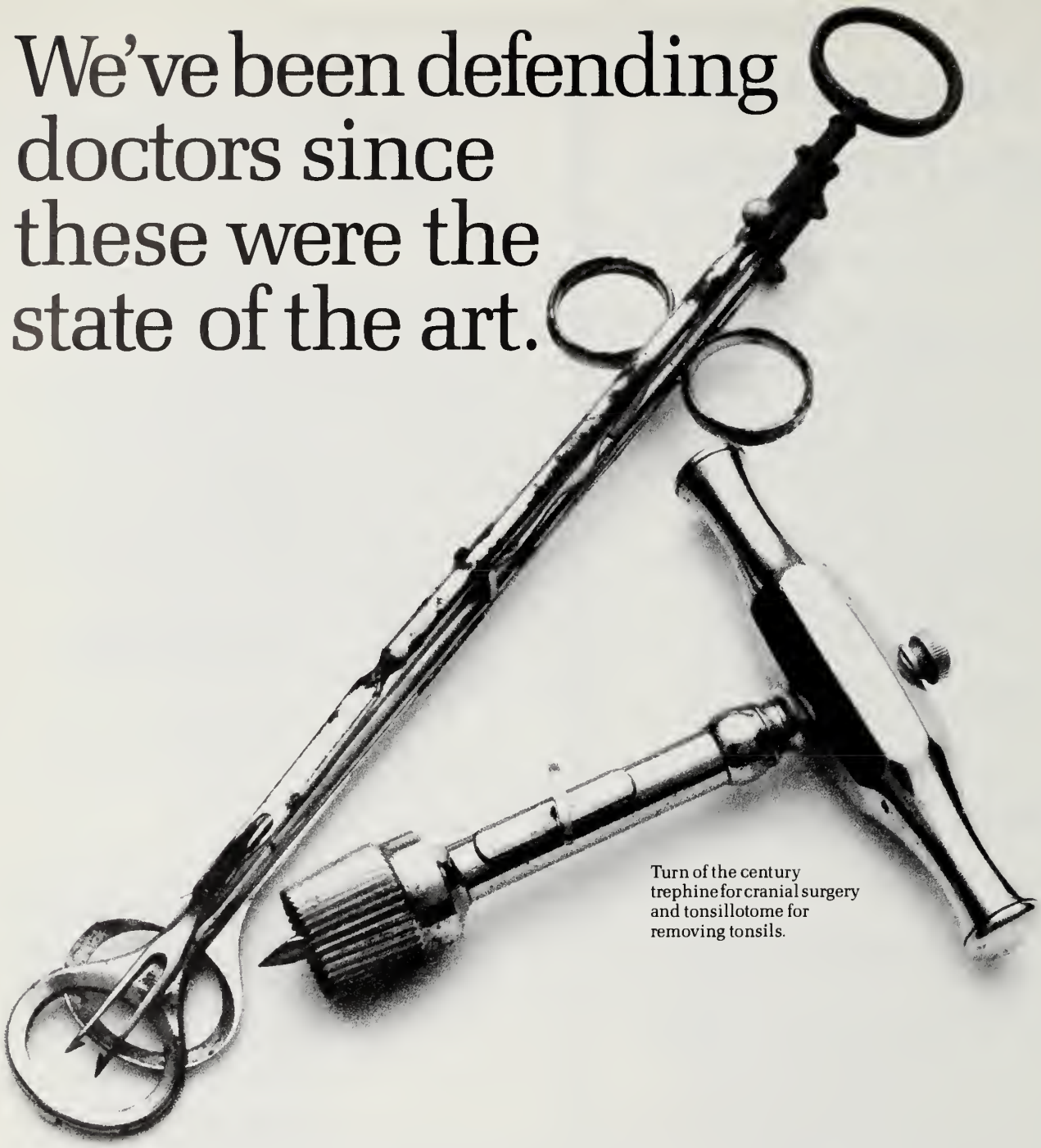
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Maternal Mortality Report

Kela Lyons, BS; John Petry, MD; John W. Greene, Jr, MD

This maternal mortality report delineates the course of a cerebrovascular hemorrhage most likely related to a basilar artery aneurysm in a patient diagnosed with severe preeclampsia. A brief discussion of this entity is presented.

Case Report

The patient was a 36-year-old gravida 1, para 0, Ab 0 white female at 36 weeks gestation who was referred to the hospital when she was noted to have an elevated blood pressure of 170/94 at a regular office visit that morning. Beginning at approximately 10 weeks gestation, the patient had been receiving monthly prenatal care and started biweekly office visits at 30 weeks. An amniocentesis was performed at 16 weeks, and throughout the pregnancy, fundal height corresponded to dates, urinalysis was normal except for occasional trace albumin, there was a total weight gain of 27 lbs, and blood pressures averaged 107/63.

Personal history of this patient was significant for an allergy to erythromycin and a previous cystoscopy. There was no prior history of any major medical illness including herpes or AIDS, and the patient did not drink alcohol or smoke tobacco. Patient's mother was deceased and had a history of epilepsy. The father was in good health as were her two sisters and one brother, and there was no history of any genetic defects.

Approximately 4 hours after admission to the hospital the patient still had an increased blood pressure of 185/87 and fetal heart tones were 145 bpm. She was monitored, instructed to be at bed rest in the left lateral position, and lab studies were ordered including CBC, SMA6, urinalysis for culture, and a 24 hour urine for total protein and creatinine clearance. An ultrasound and biophysical profile were ordered for the following morning.

The patient was transferred to the labor area after she was noted to have some mild contractions at 7 minute intervals. At the peak of contraction FHTs were noted at 10 beats per minutes requiring 30 seconds for return to baseline. The FHR appeared flat with the patient on her left side so a NST with nipple stimulation was performed. It was nonreactive and the physician was notified of these findings.

Over the next 2 to 3 hours the patient began complaining of headache and nausea and had three episodes of emesis. She was noted to have 2+ reflexes, facial flushing, and her blood pressure remained elevated. The patient was given Tylenol #3 po and 130 mg of phenobarbital IM.

At midnight, the physician was called due to a blood pressure of 198/98 and FHTs that had decreased to 115. The patient was placed on her left side which resulted in a decrease of blood pressure to 156/84 and a drop in the FHTs to 65, which then rose to 100. The OR team was called, the patient received oxygen by face mask, a foley catheter was inserted, and intravenous fluids started. Forty-seven minutes later, the patient received a bolus of 4 grams MgSO4 with infusion to follow at 1.5 g/hr. At this time there were no fetal heart tones on the monitor and delivery by C-section was deferred to pitocin induction after confirming fetal death with internal electrodes.

At approximately 6:30 the following morning, the patient developed a change in mental status with ringing in her ears and, rather abruptly, had loss of consciousness, was unresponsive, and unable to breathe. She was intubated and ventilated; however, she failed to regain consciousness. She was declared dead but was maintained on the respirator for salvage of organs. The stillborn baby was delivered by low forceps over a midline episiotomy.

Lab data showed Hb 10.7, Hct 32.2, platelets 169K, PTT 32 secs, PT 12.4 secs, fibrinogen 340, and urinalysis 5-10 WBC/hpf. A CT scan of the head was done and showed a massive hemorrhage of the brain stem centered in the pons extending from the medulla to the midbrain and with rupture into the fourth ventricle. No autopsy report is available.

This patient had a final diagnosis of severe preeclampsia with death due to cerebrovascular

hemorrhage most likely related to a basilar aneurysm.

Comment

Cerebrovascular accidents, though uncommon during pregnancy, are a leading cause of maternal morbidity and mortality.[4] Various studies indicate that strokes account for 5% to 10% of all maternal deaths with the rate of mortality for women with strokes during pregnancy ranging between 26% and 30%. The risk of stroke in the pregnant patient is 13 times the risk in the nonpregnant patient of the same age.[11] Physicians need to be aware that pregnancy can predispose to cerebrovascular accidents by producing severe acute hypertension, hypercoagulable states, and changes in vessel walls. Approximately 50% of the strokes that occur during pregnancy do so in the second and third trimesters. A similar percentage occurs in the first 2 weeks post partum.[8]

There are two major categories of cerebrovascular accidents, ischemic and hemorrhagic. In an ischemic stroke, the brain becomes infarcted from insufficient blood flow and this can be due to arteriosclerosis, cerebral embolism, or vasospasm from hypertensive disease.[7] Hemorrhagic strokes occur when intracranial bleeding results in a space-occupying lesion as evidenced by the CT scan of this patient.

Spontaneous subarachnoid hemorrhage (SAH) is the most common cerebrovascular complication of pregnancy and has been reported by Barno and Freeman to be the third most common cause of nonobstetric hypertension of malignant exacerbation of chronic hypertension can also cause intracerebral bleeding but is not commonly associated with cortical hemorrhage unless the diastolic blood pressure exceeds 110-120 mm Hg for an extended period.[7] Gibbs also reports that of 39 CVA maternal deaths in Texas (1969-1973), 25 had cerebral hemorrhage with hypertension only. Of the 25 deaths associated with hypertension, 15 could be attributed to the lethal combination of preeclampsia/eclampsia superimposed on a chronic hypertensive vascular disease.[9] Intracerebral hemorrhage from hypertension is uncommon during pregnancy, but may complicate chronic essential hypertension with superimposed preeclampsia.[8] This patient had no history of hypertension and diastolic pressures were never recorded to exceed 100 mm Hg throughout the hospital stay.

The frequency of unruptured berry aneurysms in the general population is from 0.5% to 1.0%. The incidence and risk of aneurysm rupture during pregnancy remains controversial and has been estimated to be as high as five times that in nonpregnant women of the same age group. However, a recent study suggests that aneurysms are no more likely to rupture during pregnancy, labor, or delivery than spontaneously. It is noted, though, that when rupture does occur during pregnancy the risk of death is greater than in the nonpregnant woman.[3]

The majority of cerebral aneurysms, approximately 90%, are located in the anterior portion of the Circle of Willis in both pregnant and nonpregnant patients. The remaining 10% are found in the posterior circulation with the dorsal angle of the posterior cerebral artery bifurcation point being one of the favored sites for aneurysmal development.[2] Information obtained from the CT suggests that this patient suffered from an aneurysm of the basilar artery due to its extension from the medulla to the midbrain and rupture into the fourth ventricle. In the series of both Cannell and Botterell and Robinson et al, aneurysms of the internal carotid artery were most frequent. However, in the experience of Minielly et al the basilar, carotid, communicating, and anterior communicating aneurysms were encountered with equal frequency during pregnancy.[6]

The signs and symptoms of bleeding cerebral aneurysms are the same in pregnancy as in the nonpregnant state. Although the headache associated with a ruptured aneurysm is usually described as "the worst headache of my life," such patients often report a history of a similar headache in the past. This premonitory headache, often called a "warning headache," usually represents a previous episode of aneurysmal leaking. The headaches are characteristically sudden in onset and may be accompanied by visual changes, neck stiffness, photophobia, focal neurologic deficits, or altered levels of consciousness.[10] Physical findings often include nuchal rigidity, tachycardia, hypertension, cranial nerve dysfunction, focal neurologic deficits, mild temperature elevations, leukocytosis, and mild proteinuria.[1] The pregnant woman who presents with symptoms of HTN, convulsions, proteinuria and coma represents a real diagnostic problem. Occasionally hypertension and proteinuria may lead to the misdiagnosis of atypical preeclampsia. However, severe headache and other central nervous system signs and symptoms should prompt further neurologic evaluation.[10] Besides pre-



Fig 1 — The caput of the basilar artery, ie, the dorsal angle of the posterior cerebral artery bifurcation point, is one of the favorite sites for aneurysmal development. A medium size lesion after subarachnoid blood has been washed off is seen in this photo.



Fig 2 — The cornual section of this gross specimen is from a case of a larger nonthrombosed saccular aneurysm located at the basilar artery caput.



Fig 3 — The angiogram (coronal, AP view) from the case described in Fig 2.



Fig 4 — Sagittal View. Recent hypertensive hematoma in the pons.

eclampsia, the differential diagnosis includes other neurologic conditions such as infection, degeneration or neoplasm, fulminating meningitis, cerebral abscesses, and in postpartum patients, cerebral venous thrombosis.[3]

The workup of an intracranial hemorrhage is the same for a pregnant patient as a nonpregnant patient. Radiologic and/or surgical procedures should not be postponed because of obstetric concerns. CT of the head should be the initial radiologic procedure because it is most likely to identify fresh blood and is the main diagnostic tool when intracranial hemorrhage is suspected.[12] In order to be visualized by CT, the aneurysm must be calcified, thrombosed, or greater than 1.5 cm in diameter. However, the diameter usually is less than 1.5 cm, and these are identified by angiography.[3] When an aneurysm is suspected, angiography should be performed to confirm the diagnosis, to provide for optimal therapeutic approaches, and to exclude the possibility of other coexistent intracranial aneurysms which are present in 20% of such patients.[10] The omission of vertebral arteriography may mean that a relatively remediable aneurysm in the posterior fossa is overlooked; the cost can be the patient's life.[5] Arteriography is not associated with higher maternal or fetal morbidity when the patient's condition is stable;[4] however, special shielding should be provided to protect the fetus during radiographic procedures.[2] In general, magnetic resonance imaging is not diagnostically necessary, and its safety in pregnant patients has not been determined.

The surgical management of aneurysmal SAH may be complex and requires weighing the potential risks versus the benefits to the mother and fetus vis-à-vis neurosurgical clipping of the aneurysm. Such decisions are best made in consultation with an experienced neurosurgeon skilled in the management of patients with ruptured aneurysms. Early referral after the diagnosis has been established is strongly recommended.

There is general agreement that early recognition of aneurysms and early neurosurgical intervention may lower maternal mortality. Although surgery should theoretically be performed immediately after the diagnosis is established, optimum results are usually obtained when the repair is performed 7 to 10 days after the bleed. This allows for stablization plus abatement of vasospasm and edema. Initially, management consists of supportive therapy, including observation in an ICU, prevention of convulsions, use of glucocorticoids for antiinflammatory and antiedema effects, and control of HTN.[12] Medications used in the management of an intracerebral hemorrhage during pregnancy must be considered in terms of uteroplacental blood flow, teratogenicity, and their affect on the fetus. When possible, diuretics, especially mannitol, should be avoided because of the danger of fetal dehydration. Moreover, long acting barbituates or sedatives may cause problems at the time of delivery because of depression of fetal respirations.[2]

The treatment of aneurysms is surgical for both pregnant and nonpregnant patients, however, the optimum anesthetic approach to the repair of intracranial aneurysms during pregnancy remains unclear.[6] If a neurosurgical procedure takes place during pregnancy, there seems to be no increased maternal or perinatal hazards with induced hypothermia, which is the preferred method in the nonpregnant state. If the hemorrage occurs near term, cesarean delivery immediately followed by craniotomy has proven successful.[8] There are no benefits to routine abdominal delivery in pregnancies complicated by previous successful repair of an intracranial aneurysm. However, in patients with unrepaired or incompletely repaired intracranial aneurysms, attempts should be made to minimize Valsalva efforts at the time of delivery. Continuous lumbar epidural anesthesia is indicated in such pregnancies, and the second stage of labor should be shortened with outlet forceps where indicated.[10] After successful repair of an aneurysm, there is no change in the management of the patient during the pregnancy and a history of previous craniotomy does not contraindicate further pregnancies.[6]

Mortality rates for the mother and fetus are similar to those for nonpregnant patients and are related to the severity of the SAH. In untreated patients with SAH, perinatal mortality parallels maternal mortality. In 1972, Robinson and coworkers showed that fetal mortality was 8% for ruptured aneurysms in those mothers who survived. The total incidence of fetal morbidity or mortality was 33% for aneurysms. More recent studies have shown that maternal and fetal complications, as well as mortality, can be substantially reduced with earlier diagnosis, earlier surgical interventions, and better surgical and anesthetic techniques.[2]

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Health Care Reform: AMA Positioned as Major Player in 1993

Health system reform will be one of the top three priorities for the 103rd Congress and the new Admininistration. Fortunately, the AMA is firmly positioned as a major player, thanks to the Health Access America campaign that was up and running long before presidential electioneering began.

The AMA decided that doctors did not want to wait for someone else to come along and tell us what to do. The AMA issued its own platform in March 1990 when we brought out the far-reaching plan for health care reform, Health Access America. It was one of the first comprehensive proposals for private and public change, and drew immediate nationwide attention. The plan's basic elements -- universal coverage, employer mandate, competition and freedom of choice for patients -- speak directly to core issues of access, cost control and quality care.

Some saw Health Access America as a challenge; others saw it as a model. In most proposals receiving serious attention, you will find elements of Health Access America. The bottom line is that everyone agrees that the crisis in health care access and cost has become so severe that change is needed. The public, our patients, agree that health care reform is right up there with the economy and jobs as the most urgent issues facing the nation.

As far as doctors are concerned, we are working to ensure that organized medicine has a seat at the negotiating table, to make a strong case for needed change.

You may have seen our ads in *Time*, *Newsweek*, *The New York Times*, *The Washington Post*, *US News & World Report*, *Fortune* and *Business Week* which spells out that Health Access America builds on the existing strengths of the medical and health care system. In the private sector, employers would be required to provide insurance for employees and their dependents. Government would provide coverage for the unemployed and indigent, making coverage universal. Our patients would be free to choose their own doctor, hospital and insurance plan.

We don't need a nationalized health system. We need a national health system solution: Health Access America.

The AMA, with the strong and steady support of the federation, has been a powerful advocate for change throughout this long, vigorous national debate. With your help, this kind of advocacy can become stronger. The 1992 election was the first step; every doctor has a stake in what comes next.

Be active in organized medicine. Claim your own seat at the health care reform table. It's the only way your voice will be heard ... and your voice may well make the difference in the long-term health of us all.

Materials included are excerpted from *Member Matters*, a monthly publication sent to all members of the American Medical Association.

Like Munching on a Porcupine Quill by Quill

As I write these words in December to be read in February, I pause as the torch is passed. The executive seat with the same party majority in Congress ready themselves to enact one more bit of health care legislation. I freeze with both perplexity and fear to await the outcome of this rush to judgment.

Behind closed doors the people who craft these laws will meet with HCFA officials to hammer out the fiscal means to pay for this health care reform.

Let me get out my own hammer and chisel and carve into stone my predictions. And by doing so the liberal bent in Washington can ready their vats of tar and mounds of feathers to run me out of town if I prove wrong.

Prediction #1 — The health care bill enacted will offer all things to all people at the going rate and not be able to judge the cost.

My plea. Won't somebody just stand up and say "Shades of déjà vu. We tried this with Medicare limited to those 65 years or older and nearly bankrupted the coffers."

Prediction #2 — As cost over-runs chew up the reserve funds, Congress will not have the courage to limit coverage; it will demand that hospitals and physicians bear the burden of the loss, but continue to give quality care.

My plea. Let the patient and health care recipient be partly responsible for his own care and pay into a special fund (that is actuarially sound) to pay for the high ticket items that tend to exhaust the reserve monies.

Prediction #3 — Payment for cognitive powers will be trimmed again in that this represents a major share of health care cost and is less easily defined.

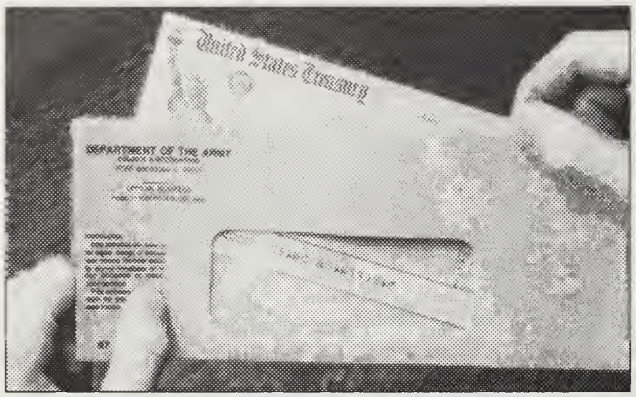
My plea. Don't ask physicians in general to endorse and encourage a plan like RBRVS, and then not be able to deliver because Congress wants to remain "budget neutral" and has to make a 2-8% across-the-board reduction in values.

I shall now cover my crystal ball with cloth and await the outcome. It won't make a monumental difference whether my predictions are correct or not. I've been chewing on this "porcupine" for a long time now.

Milton F. Miller, MD

ANESTHESIOLOGISTS AND SURGEONS: COULD YOU USE AN EXTRA $9,000?

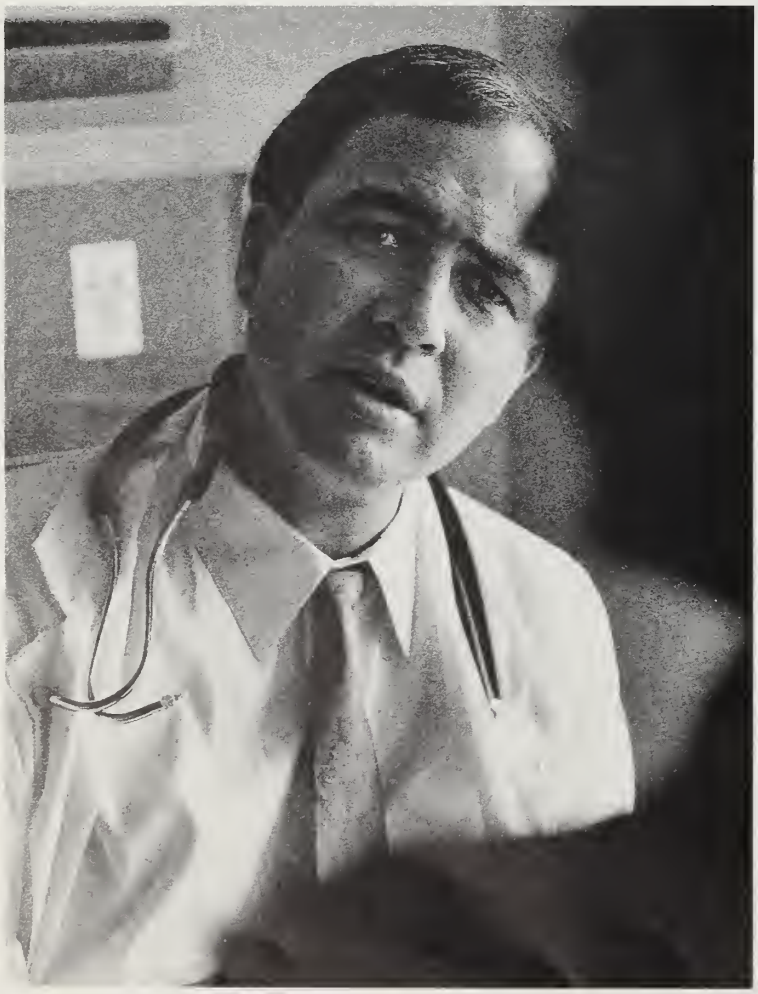
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"What impresses me most about the AMA is its willingness to take public policy positions and its ability to influence opinion," Dr. Volberding adds.

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Beryl Dodds

Providing for the Future

One of the duties of the president of the Auxiliary to the Kentucky Medical Association is to serve as a member of the Health Careers Fund Committee. The purpose of this committee is to receive and manage funds to be used for providing financial aid, without regard to race, color, or creed, to selected residents of the Commonwealth of Kentucky who plan to prepare for careers in health or health-related fields.

For the 1991-92 school year, the AKMA Health Careers Fund awarded grants totaling $3,000 to eight students from eight different schools in the Commonwealth. Seven students were awarded $4,000 for the 1992-93 school year.

In addition to the grants awarded by the state organization, many of our county auxiliaries also have scholarship or grant funds. Last year the McCracken County Medical Auxiliary raised $21,000 for their scholarship fund. This money helped fund nine full scholarships and seven "books only" scholarships to students at Paducah Community College. Additionally, they contributed $1,000 to the Health Occupations Scholarship Fund at the West Kentucky Vocational/Technical School.

In Fayette County, the Auxiliary designated $6,000 last year for scholarships in the Allied Health Field. They also awarded savings bonds to an outstanding female science student at each of their local high schools.

Jefferson County awarded $4,800 to ten students and Daviess County awarded scholarships totaling $4,000.

Hopkins County funds a $200 scholarship at the local Health Occupations School. In Pulaski County, the Auxiliary purchased two small computers plus books on science for use in the junior department of their public library. The Rowan County Medical Auxiliary contributed money to the elementary school librarian for three volumes of reference books. They also bought supplies for the Rowan County High School biology department and made a contribution to the local DARE program. Warren County Medical Auxiliary hosted a "Lunch With Santa" last year to benefit the Maydelle Johnson Funk Nursing Scholarship.

Physicians' spouses across the Commonwealth are working to improve the health of Kentuckians, not only by working directly on health projects within their communities, but also by helping to provide trained health care professionals for the future.

For membership information, contact Jean Wayne at the KMA office in Louisville. Please join us as we work today for a better tomorrow.

Beryl Dodds

AKMA President

"Physicians' spouses across the Commonwealth are working to improve the health of Kentuckians, not only by working directly on health projects within their communities, but also by helping to provide trained health care professionals for the future."

Kentucky Medical Association
PRACTICE MANAGEMENT SEMINARS

The Kentucky Medical Association, in conjunction with a number of county medical societies, will sponsor the following seminars in 1993:

February

Profitable Practice
16 - Louisville
17 - Lexington

Reception Techniques/Better Collections
18 - Lexington

CPT Coding
23 - Northern Kentucky
24 - Lexington
25 - Louisville

Financial Control of Your Practice in 30 Minutes
24 - Lexington (2-hour seminar)
26 - Louisville (2-hour seminar)

March

Marketing Techniques
10 - Northern Kentucky
11 - Louisville

How To Get Started in Practice
12 - Louisville

April

How to Deal with Managed Care Plans
7 - Lexington
8 - Louisville

For more information on these workshops, contact:
Kentucky Medical Association
(502) 426-6200

Clinton's Administration Proposal for Some Aspects of Health Care Reform

TO THE EDITOR: This information is extracted from various position statements made by Mr Clinton during the presidential campaign.

Clinton's proposal is a "pay or play" plan. Employers either offer their employees health insurance or they pay into a public plan. A Federal Health Board will be established to set uniform benefits that all insurers and the public plan would have to provide, including ambulatory physician services, inpatient hospitalization, prescription drugs, basic mental health services, and preventive health care.

Clinton's plan would encourage insurers, institutions, and providers to form local health networks, which would manage care, negotiate fees, and operate under a global budget.

Clinton's proposal would require community-rated insurance and provide protections for small employers.

With regard to controlling costs, Clinton would use the Federal Health Board to establish national and state budget targets and to develop an all-payor reimbursement system. He would reduce administrative wastes through streamlined insurance claims processing, reduce billing fraud, and provide updated medical practice guidelines. The Board also would control the unnecessary spread of technology through its recommendations and incentives for "sensible capital budgets, including the shared use of technology."

The plan would reduce drug prices by eliminating tax breaks for drug companies that raised their prices faster than peoples' incomes and would limit the deductibility of drug company marketing and lobbying costs.

With regard to professional liability reform, Clinton believes alternative dispute resolution mechanisms should be available in every state and that medical practice guidelines can help establish better directions as to what constitutes medical malpractice.

Clinton's plan has an extensive, long-term care component.

Clinton would accelerate the FDA approval process.

There are several areas of health care reform focus that *do not* appear in Clinton's health care reform plan. Specifically, he does not mention far-reaching proposals with regard to professional liability reform. The specific areas *not* mentioned are:

1. Cap on non-economic damages
2. Eliminate joint and several liability for non-economic damages
3. Eliminate the collateral source rule
4. Require structured awards as opposed to lump sums
5. Promote pre-trial alternative dispute resolution
6. Require the party refusing to use the alternative dispute resolution mechanism to pay the other party's attorney fees.

There is no proposal in the Clinton plan to increase funding for community health and migrant health centers and the National Health Service Corp.

William H. Mitchell, MD

"Does Kentucky Need a Primary Medical School?"

TO THE EDITOR: I read the report of W. J. Hueston, MD, "Does Kentucky Need A Primary Medical School?" in your November 1992 issue.

The establishment of an additional medical school would aggravate the present situation of an oversupply of physicians. The existing medical schools must create an environment where about 50% of the graduates go into primary care. These needed changes might require action at the national level: limiting the number of residency spots with a maximum being set at, for instance, 110% of the number of US medical school graduates, with 50% of these slots in primary care. As regards inducing students to go into the primary care specialties, the state should require repayment of public monies used by students during their medical training for all students going into specialty (as opposed to primary) care training. I would estimate this would amount to about $100,000 per student. This money could be used to reduce the expenses of those students who are going into primary care, to support research, and to pay for clinics to care for the uninsured. Service obligations for all young physicians as a method of caring for the uninsured are preferable to universally mandated insurance.

Biomedical research has been artificially limited in medical schools by the drive towards ever increasing levels of subspecialization, whereas areas such as increasing the efficiency of primary care services to the general public have not been addressed. One symptom of the problem is evident in the theme of the cover story of this issue, "Survival of Persons with AIDS in Kentucky." If viewed from the point of efficiency, that is of years of life gained for dollars spent, AIDS must be one of the least cost effective diseases to treat. Our profession must emerge from behind a phalanx of subspecialists and give greater weight to efficient and affordable care for the average person. The alternative is complete government control, not just insurance-wise, but rather of the everyday provision of services to patients.

F. Andrew Morfesis, MD

PEOPLE

The 1992 Bluegrass Health Heroes Awards Presentation to recognize leaders in the health care industry was held recently in Lexington. Nominees for this award are persons or entities providing health care services from an office located in the 17-county Central Kentucky area. "Health Heroes" are chosen from the group of nominees by a committee of medical professionals and laymen selected by the Fayette County Medical Society.

The following KMA and AKMA members were among this year's "Health Heroes":

Franklin B. Moosnick, MD, a Lexington internist for 45 years, was recognized for his numerous accomplishments in education, community service, and organized medicine. He has served as president of the Fayette County Medical Society, Kentucky Diabetes Association, Kentucky Heart Association, and Kentucky Society of Internal Medicine. As a pioneer in the medical arena in the Bluegrass region for many years, he was prominent in promoting polio immunization, developing diabetes detection programs, training programs for paramedics, and innovative techniques of needle biopsy of the liver. Dr Moosnick has received numerous awards including the President's Cup from the Lexington Rotary Club and the National Conference of Christian and Jews Brotherhood Award for Central Kentucky. In 1990, the American Heart Association established the Franklin Moosnick Service Award in recognition of his guiding influence on the American Heart Association since 1967.

Philip R. Curd, MD, a family practitioner in McKee (Jackson County), received the award for his dedication and unassuming service to rural Kentuckians by establishing a clinic in a needy area. Dr Curd began practice alone in McKee in 1973 in a little white frame house that eventually gave the clinic its name. Today, the White House Clinic has almost 40 employees, including two additional physicians — **David A. Greene** and **John S. Belanger** — two dentists, and three nurse practitioners. Dr Curd also received recognition in September 1992 when he was named recipient of the Sargent Shriver Award for Humanitarian Services.

Russell L. Travis, MD, a Lexington neurosurgeon, was honored for his significant contributions to the public good and his unflagging dedication to the health care of Kentucky's indigent population. Dr Travis has served as chairman of the Kentucky Physician's Care Program since its inception in 1985. He has devoted many years to organized medicine and currently serves as Chairman of the KMA Board of Trustees.

Doris Rosenbaum (Mrs Harold D.), Lexington, was chosen for her tireless efforts in causes related to the reduction of breast cancer mortality, most notably through The Thursday Group, one of the outstanding breast cancer support groups in the United States. She spearheaded a drive to get the 1990 Kentucky General Assembly to pass two very important pieces of relevant legislation — HB 62 and SB 41. The first of these mandates coverage of screening mammograms by health insurance carriers writing policies in Kentucky, and the second provides funding for screening mammography of medically indigent women. Under the provisions of SB 41, Mrs Rosenbaum was appointed Chairperson of the Breast Cancer Advisory Committee to the Department for Health Services.

Sarah Moore (Mrs Glenn I.), a registered nurse in Lexington, accepted the award on behalf of the Nathaniel United Methodist Mission Health Clinic. Mrs Moore is executive director of the Clinic, which was recognized for the care it has provided since 1978 to the less fortunate of the community. With an annual budget of only $8,000, the Mission was able to treat 1631 people in 1991. Their sparse budget is augmented by more than 40 dedicated professionals, all volunteers, who donate their time and talents every month to provide care to the indigent.

UPDATES

X-ray Offers Hope for Victims of Brain Tumors

The University of Louisville reports that a new "knifeless" technique is allowing doctors to use X-rays to treat brain tumors when conventional surgery is considered too risky.

Surgeon **Christopher B. Shields, MD,** and a team of doctors use stereotactic radiosurgery to battle the cancer. They aim highpowered X-ray beams toward the tumor, destroying the cancer without harming healthy tissue.

According to the report, the 30-minute, outpatient procedures gradually shrink tumors without causing any dangerous side effects.

Grant to Boost Supply of Generalist Physicians

The Robert Wood Johnson Foundation has awarded the U of L School of Medicine a planning grant aimed at increasing the supply of generalist physicians.

Additionally, Governor Brereton Jones has designated the Trover Clinic in Madisonville as an off-campus teaching center for U of L. The Trover Clinic will play a major role in the planning grant.

With the grant award, the Robert Wood Johnson Foundation challenges the U of L School of Medicine, in collaboration with state government, private practices, hospitals, public and private insurers, and community health centers, to increase the supply of generalist physicians. Generalists include family practitioners, general internists, and general pediatricians.

During the planning stage, U of L will develop admissions, curriculum, and residency approaches directed toward increasing the number of graduates who become generalist physicians.

One aspect of the planning phase will be the development of a special generalist physician track. Students in this track will have specific generalist experiences and may spend up to 18 months at the Trover Clinic.

The Trover Clinic Foundation, established in 1957, is dedicated to teaching and research in the health care field. It has had continuous educational relationships with U of L for more than 20 years.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Calloway

Jon M. Gustafson, MD — N
300 S 8th St #380W, Murray 42071
1987, Oral Roberts School of Med

Christian

Dennis C. Harper, MD — IM
213 Village Green Dr #E7, Hopkinsville 42240
1983, Medical Col of Georgia

Daviess

Kishor N. Vora, MD — C
2211 Mayfair Ave #311, Owensboro 42301
1983, Grant Medical Col, India

Franklin

Gary C. Mallis, MD — PD
601 Leawood Dr, Frankfort 40601
1983, Albert Ludwig U, Germany

Grayson

Gary E. Yochim, DO — OBG
908 Wallace Ave #103, Leitchfield 42754
1985, Kansas City Col of Osteopathy

Hopkins

Christian O. Debranin, MD — ONC
Mahr Cancer Ctr, Madisonville 42431
1969, U of Athens

Hector L. Garcia, MD — C
PO Box 251, Madisonville 42431
1980, U of Puerto Rico

Elbert C. Lee, MD — P
200 Clinic Dr, Madisonville 42431
1987, U of Michigan

Laura Marrero, MD — N
PO Box 251, Madisonville 42431
1979, U of Puerto Rico

Rennan M. Quijano, MD — PD
3010 Buffalo Tr, Madisonville 42431
1982, Cebu Inst of Medicine

Thomas P. Short, MD — GE
3060 Buffalo Tr, Madisonville 42431
1982, Ponce School of Medicine

Angeli D. Suarez, MD — PD
3010 Buffalo Tr, Madisonville 42431
1982, Cebu Inst of Medicine

Jefferson

Benjamin Djulbegovic, MD — HEM
902 Lone Tree Ct, Louisville 40223
1976, U of Sarajevo

George H. Goldsmith, Jr, MD — HEM
7003 New Bern Ct, Prospect 40059
1970, Harvard

Magdy W, Khalil, MD — AN
3706 Utica Pike, Jeffersonville 47130
1978, Cairo U

David A. Petruska, MD — S
3032 Wedgewood Way, Louisville 40220
1985, U of Southern California

Gary A. Yurow, MD — C
225 Abraham Flexner Way #305, Louisville 40202
1984, George Washington U

Knott

Mouhamed A. Albaree, MD — IM
PO Box 849, Hindman 41822
1984, Damascus U

Madison

W. David Todd, MD — P
PO Box 511, Berea 40403
1972, U of New Mexico

Marion

Gregory L. D'Angelo, MD — ORS
330 Loretto Rd #400, Lebanon 40033
1982, McMasters U

Mason

Nancy E. Guttman, MD — FP
910 Kenton Station Dr, Maysville 41056
1989, Medical Col of Ohio

McCracken

Joseph C. Curtsinger, Jr, MD — S
1532 Lone Oak Rd #3, Paducah 42003
1980, U of Louisville

William Kornfeld, MD — P
210 Illinois St, Paducah 42001
1954, Harvard

James P. O'Rourke, MD — TS
2515 Broadway, Paducah 42001
1982, U of Illinois

Morgan

Carmen C. Purl, MD — FP
601 E Margaret, Wilmore 40390
1985, U of Texas

Northern Kentucky

Mark R. Rosenberg, MD — P
7205 Dixie Hwy #5, Florence 41042
1987, Duke U

Steven L. Willett, MD — OBG
111 Feldman Ln, Wilder 41076
1987, Ohio State U

Pike

Alfredo L. Salcedo, MD — U
PO Box 3445, Pikeville 41502
1962, Far Eastern U

In-Training

Jefferson

Thomas L. Lazoff, MD — PMR
Keith Jay Owens, MD — OBG
Deward H. Voss, MD — OBG

St. Elizabeth's

Julie A. Parke, MD — FP

Trover Clinic

Kenneth L. Bain, MD — FP
Kenneth W. Cloern, MD — FP
Robin M. Floyd, MD — FP
Gregory L. Fuqua, MD — FP
William R. Hoffman, MD — FP
Terry Steve McCuiston, MD — FP

DEATHS

Karl H. Strand, MD
Somerset
1932-1992

Karl H. Strand, MD, a pathologist, died October 15, 1992. Dr Strand graduated from the University of Zurich, Switzerland, in 1966 and was an active member of KMA.

Charles R. Shaw, MD
Highland Beach, FL
1904-1992

Charles R. Shaw, MD, a retired general practitioner, died October 25, 1992. A 1934 graduate of the University of Louisville School of Medicine, Dr Shaw was a life member of KMA.

Alfred Mitenieks, MD
Hopkinsville
1908-1992

Alfred Mitenieks, MD, a retired neurologist, died November 1, 1992. Dr Mitenieks graduated from the University of Helsinki, Finland in 1934 and was a life member of KMA.

KMA Member . . .
Auxilian . . .

Our readers are interested in the important events occurring professionally in the lives of their fellow members. Do you, or someone you know, have a newsworthy note to submit for possible publication in your *Journal of the KMA*?
If so, please submit in writing to:

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Louisville, KY 40222-8512

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502/426-6200

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REFURBISHED MEDICAL EQUIPMENT — Omega automatic blood pressure unit — new; Ritter procto table; portable x-ray; Shampaine OB-GYN table; autoclaves; infant & adult scales — color-coded — excellent condition; lab centrifuges; mixed bag of surgical drapes, towels, instrument wraps in 50# boxes — $100.00 + shipping. Call Bernard Medical Resources, 1/800/892-3716; FAX 606/581-5205.

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PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide expenence indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphoknase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphoknase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% nse in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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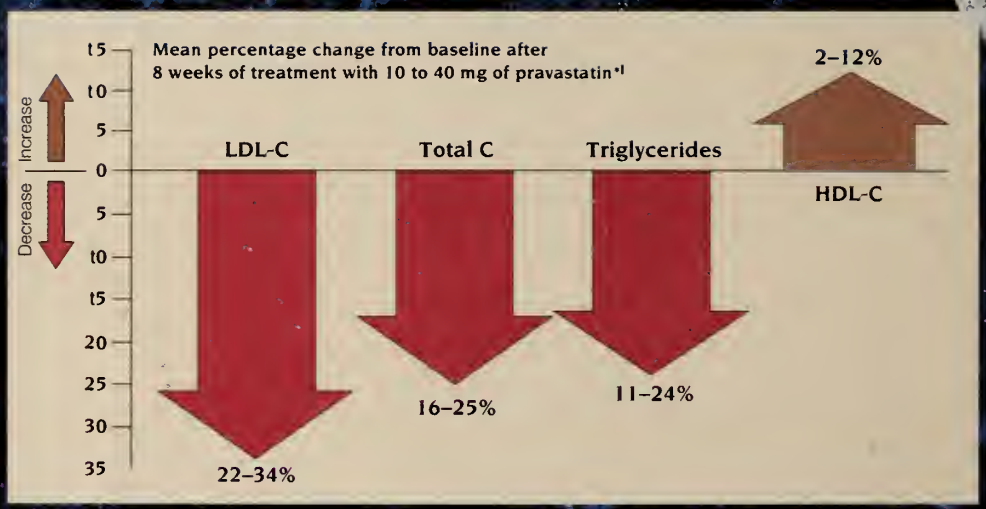
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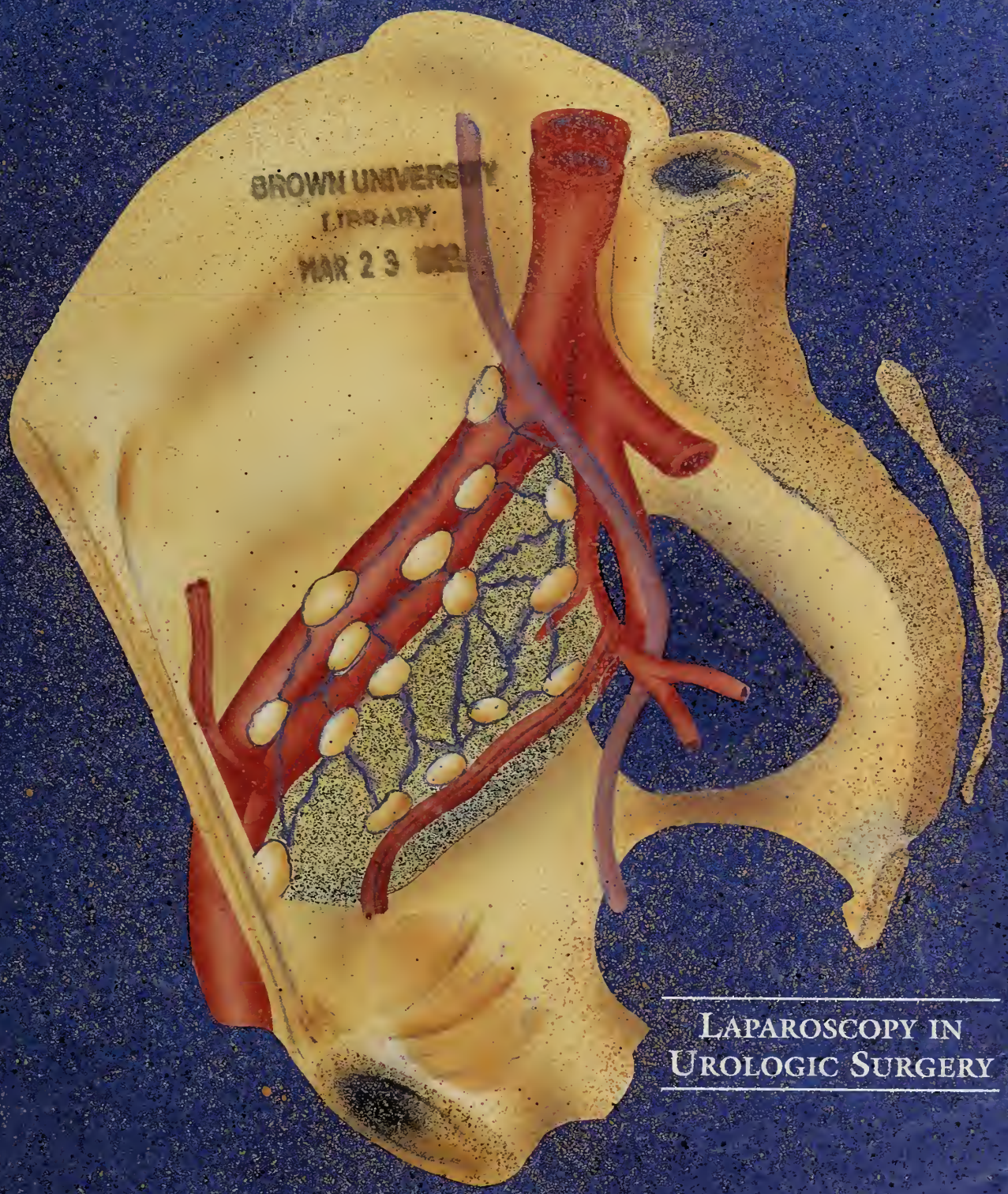
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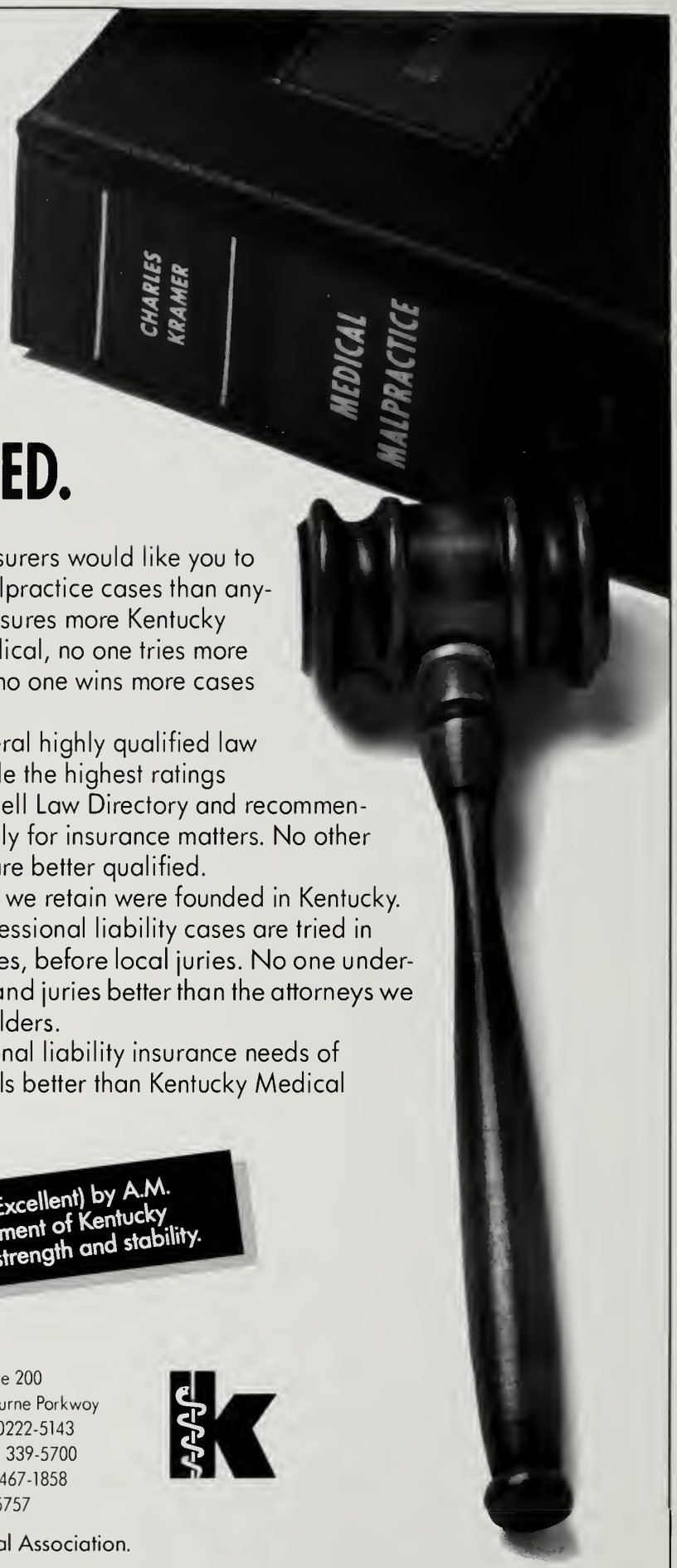
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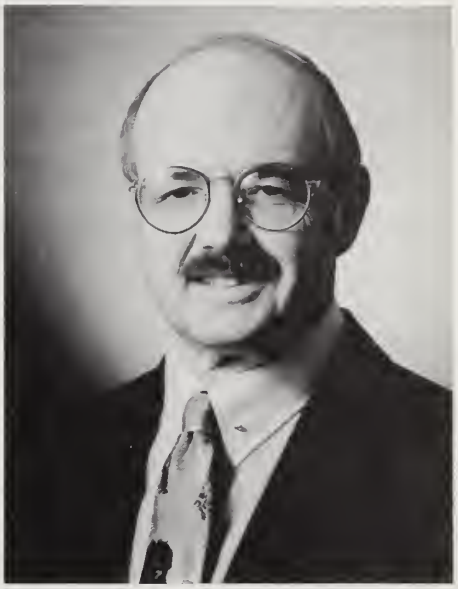
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Health Care Reform



Russell L. Travis, MD

Health care reform has grabbed the attention of the American public. A day seldom passes without some criticism of our health care system in a newspaper or television story or in a speech by a major political figure. The need for change is no longer debated; the questions now are what kind of change will occur, and in what direction will reform lead the United States health care system?

To date, the debate over health care reform has primarily focused on finding the best way to ensure that all Americans have access to a health insurance policy. The issue of how to solve the nation's sharply rising health care costs, now increasing at about $95 billion per year, has been secondary. Recently, the attitude has shifted to reining in costs to radically change the nation's health care system for the future.

There is a growing consensus that our country's health cost problem cannot be addressed adequately without enacting some form of a national health plan.

Robert J. Blendon of the Harvard School of Public Health summarized the choices for health care reform in a recent book, *The Future of American Health Care, Volume II, Reforming the System.* Dr Blendon feels that the debate on health care reform seems to be focusing on a choice between two fundamentally different strategies for containing the growth of health care costs. Costs will be controlled either through market competition or through government fee-setting and budgets. Proponents of each school are either outstanding economists or health policy experts. From the same facts, cost figures, and health care system, they draw diametrically opposed conclusions regarding the shape of reform needed. Will Americans prefer to have their elected government play the central role in determining the priorities and general direction of their personal health care system, or will they prefer a restructured market system, with numerous private health care entities making hard choices and setting the general directions for personal health care? We are moving in the direction of being forced to choose between two systems: all-payer/global budgets or market competition.

Proponents of the all-payer/global budget school favor the enactment of an all-payer (or even single payer) health insurance system and would link it to a prospectively established annual budgetary limit on the nation's health expenditures. Health care decision and priority setting would take place within the context of an agreed upon spending limit on almost all private and public health expenditures. This group thinks that the costs of health care are determined principally by the behavior of suppliers of the service and ignore the consumer; therefore, public policy should focus on controlling the financial behavior of providers and not consumers. This concept requires direct governmental intervention and restricts the possibility of marketplace competition in health care. This requires limits on professional licensure, practice, and accreditation. In general, this involves direct governmental intervention in all aspects of health care delivery, not only with rate setting but also with limits on professional licensure and practice, accreditation, medical speciality certification, control of licensure boards, and general control of who can practice and prescribe drugs.

"In spite of the attempts of the press and others to drive a wedge between those who provide health care and legislators who must consider reform, we must remain involved. Health care reform in some shape is inevitable."

The other school of thought advocates the adoption of competitive

"One thing is certain — there is no serious support for status quo."

market reforms to reduce health care spending. The approach and reasoning of this group of scholars and policymakers is very similar to those proponents of deregulation and increased competitive activity for the airline, trucking, banking, and long distance telephone industries. They believe that the government needs to revamp its policies of price setting and planning to encourage more competition in health care, as it has done in other industries.

In particular, the federal government would provide substantial tax incentives to individuals and business to purchase less costly health plans such as HMOs or managed care plans. Individuals who do not enroll in the less costly plans would pay considerably higher taxes and premiums. Advocates of this approach believe that with the right income tax incentives for individual consumers and the proper pro-competitive regulatory structures, there would be a sharp rise in the demand for new managed care plans and insurers competing for enrollees based on the lowest price and most effective use of health resources. After some time, the less efficient health plans would go out of business so that only the best quality, cost effective plans would be left in most regions.

Under this strategy, there would be little need for government to seek to influence the behavior of health care providers, ie, no need for price controls or rate setting for hospitals or doctors.

As President-Elect Bill Clinton takes office, there is some insight into future direction for health care reform. On December 7, 1992, each member of Congress was provided the book, *Mandate for Change.* This book was produced by the Progressive Policy Institute. The Progressive Policy Institute is a project of the Democratic Leadership Council, an organization Clinton helped to create and which he headed from March 1990 to August 1991. He was one of the founders of the Progressive Policy Institute. In the chapter of that book entitled "A Plan for Affordable Universal Health Care," the author discusses the differences in government single-payer national health care budgets and price setting versus what they favor and describe as "managed competition." The "Progressive Plan" for health care reform stresses "reliance on consumer choice and well-structured markets rather than publicly-regulated prices to control cost; reliance on private health coverage rather than on extended public programs (such as Medicaid) to achieve universal access to care; tax reform to make government subsidies more progressive and less inflationary; and better incentives and information to help providers focus on the highest-value forms of health care."

In discussing rate setting the author states, "Price controls-public regulation of the price and volume of most medical procedures . . . appear to promise and speed certainty and accountability in restraining health care costs. But their proponents ignore the limitation of Medicare price setting and, more generally, the dismal record of price controls and central planning, from US gas lines in the late 1970s to the worldwide fall of command economies in the past 4 years. . . . Price controls, which have little means to reward high-quality medicine, would lock in or exacerbate the inefficiencies of our current health care system. They would tend to cap prices for good and bad providers in equal measure."

"Most Americans have little understanding of the differences in the strategies for health care reform. We will have to play a major part in participating in the debate and in educating the public (our patients) about the different policies and their impact on health care."

Most Americans have little understanding of the differences in the strategies for health care reform. We will have to play a major part in participating in the debate and in educating the public (our patients) about the different policies and their impact on health care.

One thing is certain — there is *no* serious support for status quo. One other quote from the book, *Mandate for Change,* stresses the need for involvement in the debate — almost like blackmail. "The fact that public budgeting remains an option may well prompt cooperation from some in the provider community to understand that their enlightened self-interest lies with better markets, not more regulation of prices and volume."

In spite of the attempts of the press and others to drive a wedge between those who provide health care and legislators who must consider reform, we must remain involved. Health care reform in some shape is inevitable.

Hubris in its broadest definition is the feeling that the problems of the past will not effect our future — avoid hubris.

Russell L. Travis, MD
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Laparoscopy in Urologic Surgery: Modern Applications of the Cystoscope

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History of Laparoscopy

Derived from the Greek *lapara* (flank) and *skopein* (to examine), the term "laparoscopy" is defined as the endoscopic examination of the interior of the abdomen by means of a laparoscope. When the thoracic cavity and the organs of the pelvis are examined, the more accurate term is "cavitoscopy."

Although urologists were the first specialists to perform endoscopic procedures routinely, they were slower to make use of laparoscopic techniques than were the gynecologists who popularized diagnostic laparoscopy and introduced the concept of performing procedures such as tubal ligation via a separate puncture site. Laparoscopy moved into the field of general surgery in the 1980s. Semm described a laparoscopic appendectomy in 1983,[1] and Frimberger performed the first laparoscopic cholecystectomy in 1987.[2]

However, urologists have again taken the lead in the development of new instrumentation, such as high-performance morcellators and impermeable bags for removing solid tissue and organs, and of new techniques, such as laparoscopic nephrectomy[3] and laparoscopic radical prostatectomy (W. Schusessler, MD, personal communication). The outlook for laparoscopic procedures appears excellent. Dr Ralph Clayman has suggested that before the year 2000 most surgical procedures will be performed using some form of minimally invasive technique (Ralph Clayman, MD, personal communication).

Laparoscopic Techniques

Psychological and physical preparation of the patient for pelviscopy and laparoscopy have been described in detail by Semm.[4] Before surgery is begun, patients should undergo some form of mechanical bowel preparation for decompression. A drainage catheter should be placed in the patient's bladder. If a lengthy procedure is anticipated, a nasogastric tube should be placed just before the procedure begins.

The pneumoperitoneum is usually created by inserting a Veress needle into the peritoneal cavity at the level of the umbilicus. Carbon dioxide is the agent of choice for insufflation in any procedure likely to require electrocautery. After a static intra-abdominal pressure of 14 mm Hg is achieved, a larger (10 mm) trocar and sheath are passed into the peritoneal cavity. The laparoscope is passed through this sheath, and diagnostic evaluation of the intra-abdominal contents is carried out. The pneumoperitoneum is maintained by means of an automatic high-flow regulator. Additional working ports required for the procedure are placed under direct vision.

When patients have had prior surgical incisions near the umbilicus, the surgeon should consider alternate sites for the trocar. Mini-laparotomy incisions may be required to facilitate safe placement of the trocar. If adhesions to the abdominal wall are encountered, they must be taken down.

At the conclusion of the procedure, the surgeon must perform a careful examination for hemostasis and absence of bowel or vascular injuries. Then the accessory ports should be removed under direct vision. All carbon dioxide should be expelled to minimize postoperative discomfort, and the primary sheath should be removed. If sheaths 10 mm in diameter or larger are used, the fascia of the puncture sites through which they were introduced should be closed with sutures. Smaller port sites can usually be closed with Steristrips alone. Depending on the type of procedure performed, most patients can be discharged within 24 to 48 hours. The patient's return to full activity can often be expected in five to seven days.

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Complications of Laparoscopy

In general, laparoscopic procedures can be safely performed on patients for whom the degree of risk associated with more invasive procedures would be unacceptably high. However, there are several absolute and relative contraindications for laparoscopy. Absolute contraindications include pregnancy, intolerance of anesthesia, severe bleeding disorders, complete intestinal obstruction, and hypovolemic or septic shock. Some relative contraindications include morbid obesity, large abdominal pelvic masses, recent myocardial infarction, multiple abdominal scars, chronic pulmonary disease, and partial intestinal obstruction.

Physicians must explain to patients undergoing laparoscopic procedures that a formal celiotomy may be required if laparoscopy is not successful in correcting the problem or if complications develop. Potential complications, which should also be explained to the patient, include injury to vessels, bowel, or bladder. Large vessels can be injured during the initial "blind" trocar insertion or during intraoperative dissection. Uncontrolled bleeding requires laparotomy and vascular control. Injury to the small bowel can occur during insertion of the Veress needle, but such injuries can usually be repaired via laparotomy, as can injuries to the colon. A postoperative "acute abdomen" should lead the surgeon to suspect an unrecognized bowel injury, and exploration should be carried out. More serious complications, such as necrotizing fasciitis, have been reported, but these complications can be prevented by meticulous preparation prior to and during the procedure.

The complications of laparoscopic surgery can be minimized if they are anticipated and prepared for properly. A thorough understanding of the underlying anatomy is essential. Proper testing of the equipment prior to the procedure will minimize unanticipated delays that might otherwise cause the procedure to be aborted. The surgeon should be well trained in the general techniques and instrumentation of laparoscopy, and an experienced laparoscopic operative team should be present.

Current Directions in Urologic Laparoscopy

Bilateral Pelvic Lymph Node Dissection

For patients with newly diagnosed prostate cancer, initial studies are directed toward determining the extent of disease. Because surgical excision of the prostate or radiation therapy to the prostate is only effective if the disease is confined to the gland, accurate examination of the pelvic lymph nodes, the first site of metastasis, is important. The obturator, hypogastric, and external iliac lymph nodes are the primary drainage pathways for prostate cancer.[5] Current diagnostic techniques for detecting lymph node metastasis, including computed tomography (CT) scan, magnetic resonance imaging (MRI) scans, and lymphangiography, have focused on these nodes. Unfortunately, however, these techniques have only an overall 50% accuracy rate.[6,7,8] Therefore, bilateral pelvic lymph node dissection is required for accurate staging of the patient's tumor.

In the past, a separate procedure for bilateral pelvic lymph node dissection was not routinely performed prior to laparoscopy because of the high morbidity rates associated with this procedure; the complication rates have been estimated at 12% to 24%, including a 5% to 10% likelihood of wound infection, deep venous thrombosis, or pulmonary embolism and a 10% likelihood of lower extremity edema.[9,10] Therefore, patients undergoing radiation therapy or perineal prostatectomies did not have the benefit of accurate staging. The operative time for surgical pelvic lymph node dissection performed as an isolated procedure is 2 to 2½ hours. The patient's hospital stay is approximately 3 to 5 days. The advent of laparoscopic surgery has allowed surgeons to perform a pelvic lymph node dissection with much less morbidity and minimal recovery time. Laparoscopic techniques have allowed us to expand the role of bilateral pelvic lymph node dissection because of the low morbidity of this procedure.

Laparoscopic bilateral pelvic lymph node dissection is performed using three lower-abdominal accessory ports. The anatomical limits, seen in Fig 1, include the area subtended by the external iliac vein laterally, the pelvic floor inferiorly, and the hypogastric vasculature medially. All lymphatic tissue within this triangle should be removed, including the lymphatics around the obturator nerve. The dissection is begun by opening the lymphatic and fatty tissue over the external iliac vein. This tissue is stripped off the vein and the pelvic sidewall. The obturator nerve is identified, and the distal extent of the lymphatic tissue as it enters the inguinal canal is ligated with a large hemoclip. The lymphatic package is teased off the obturator nerve and ligated proximally at

the bifurcation of the internal and external iliac arteries. The package is removed through a 10 mm port. If a suspicious lymph node is identified, it can be excised separately.

A study by Winfield et al indicated that the number of nodes removed by laparoscopic surgery is similar to the number removed by standard pelvic node dissection.[11] The authors reported no case in which positive nodes were missed by laparoscopic surgery. As with other laparoscopic procedures, the patient is ambulatory the evening of surgery and is generally discharged the next day. The operative time, currently 2 to 4 hours, is decreasing as our expertise with this technique improves.

When laparoscopic surgery is performed, the morbidity associated with staging prostate cancer patients is significantly reduced. In one of our patients, laparoscopic techniques allowed us to visualize and remove a large lymph node confirmed by pathologic examination to represent adenocarcinoma of the prostate. The patient was discharged from the hospital on the day following surgery. Our experience indicates that patients with clinically localized prostate cancer can undergo laparoscopic bilateral pelvic lymph node dissection before they either receive radiation therapy or undergo a perineal prostatectomy. However, we do not believe that laparoscopic node dissection is indicated for patients undergoing a radical retropubic prostatectomy unless the CT scan, MRI, Gleason grade, or tumor size is suggestive of metastatic disease. If metastatic disease is indicated, a bilateral pelvic lymph node dissection done at the time of radical retropubic prostatectomy is associated with minimal morbidity and is the most cost- and time-efficient method of determining the status of the pelvic lymph nodes.

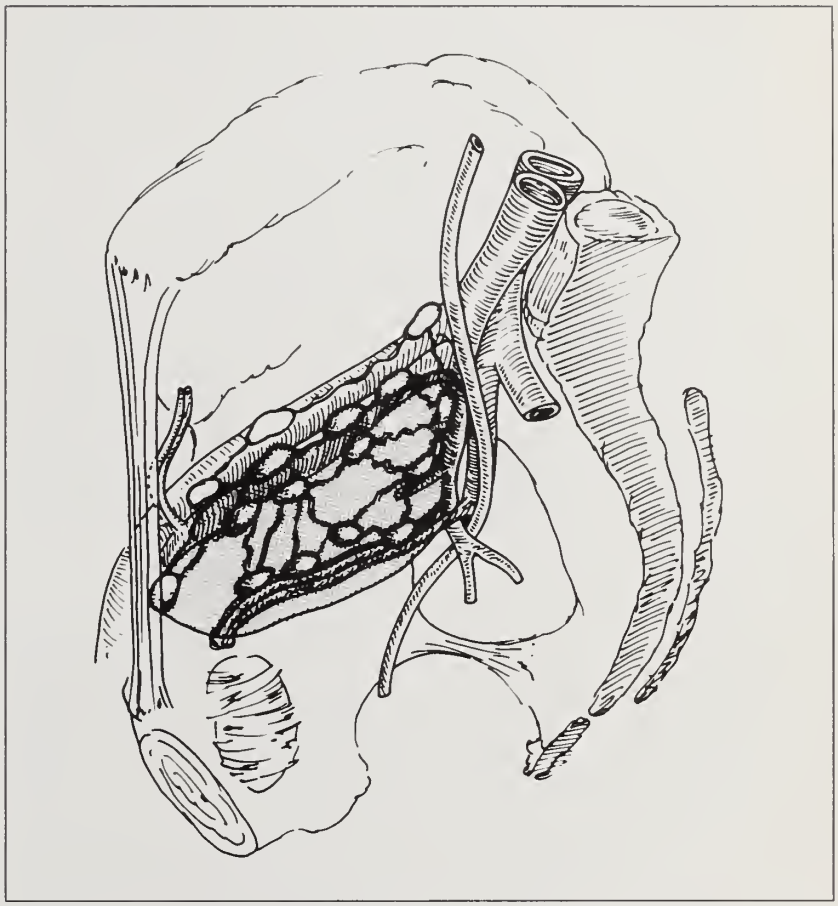


Fig 1 — Shaded area indicates the anatomical limits of a pelvic lymph node dissection for prostate cancer. (Reproduced from* Urologic Surgery *4th ed. Glenn JF, editor. Philadelphia: JB Lippincott Co; 1991:612.)

Laparoscopic Varicocele Ligation

A varicocele is an abnormal dilatation of the pampiniform plexus. In men, the incidence of varicocele is approximately 15%.[12] Varicocele is believed to be a significant contributing factor in male infertility, because the incidence of this condition in association with infertility is 20% to 40%.[12] Large varicoceles are often painful. Ligation of the spermatic veins is the treatment of choice, and several surgical procedures have been developed to maximize ligation of primary and collateral veins. The two most commonly accepted procedures are the inguinal and retroperitoneal high ligation techniques. Both are associated with significant postoperative discomfort that may prevent return to full activity for several weeks. Alternative techniques, including percutaneous embolization of the veins, have been developed, but the failure rates of these procedures are as high as 15%,[12] and the possibility exists that the occlusive devices may migrate to other locations.

Laparoscopic ligation of the spermatic veins is easy to perform and has several advantages over the traditional approaches.[13,14] First, identification and preservation of the spermatic artery are more easily accomplished in the magnified field. Second, bilateral varicocele ligation can be accomplished without a separate incision. Third, postoperative pain is significantly reduced, and patients return to full activity in days instead of weeks.

The peritoneum overlying the spermatic vessels proximal to the vas deferens is incised. The spermatic artery is identified and spared. The two or three spermatic vein branches usually present are ligated with titanium clips and divided. Patients are usually discharged on the same day and can resume full activities in 2 to 4 days.

To date, no complications associated with this procedure have been reported. This procedure is rather new, and neither lengthy follow-up periods nor long-term comparisons to traditional approaches have yet been reported. However, improvements in sperm count have been documented by semen analyses, and patients undergoing the procedure for pain have experienced resolution in all reported cases. This technique appears to provide an attractive alternative to the more traditional approaches for the treatment of varicocele.

Impalpable Undescended Testes

The surgical management of impalpable undescended testicles presents special problems. Pediatric urologic laparoscopy has recently made significant contributions to the diagnosis and management of impalpable testes.[15, 16, 17] Initial concerns about the safety of performing laparoscopy in children less than 2 years of age have been abated by recent reports confirming the safety of the procedure in children as young as 12 months or even 3 months of age. The rationale of employing laparoscopy for localizing the impalpable testis in young children is essentially threefold. First, and most importantly, of all the available methods of preoperative testicular localization (ie, arteriography, venography, herniography, radionuclide scanning, ultrasonography, CT scanning, and MRI), laparoscopy is the only modality with success rates approaching 100%. Second, non-laparoscopic techniques are difficult to perform on children, may require a separate general anesthesia for the localization procedure itself, may impose a significant radiation burden on such young patients, and are fraught with false-negative and false-positive results. Third, definitive surgical maneuvers such as orchiectomy or the first stage of a planned Fowler-Stephens operation can sometimes be performed via the laparoscope, thus adding a therapeutic dimension to a diagnostic procedure.[18, 19] Therefore, the current consensus is that, when followed by definitive surgery under the same anesthesia, laparoscopy is the investigative procedure of choice for locating an impalpable testicle. If the testicle appears salvageable or the process is bilateral at that juncture, the first stage of a Fowler-Stephens procedure can be performed using hemoclips, and 4 to 6 months later the testes can be repositioned in the scrotum through bilateral groin incisions.

Because of its extremely high diagnostic accuracy, laparoscopy affords additional advantages. In approximately 20% of cases, the testicle is absent,[20] and if its absence can be confirmed laparoscopically, an open surgical exploration can be confidently omitted. Exact laparoscopic localization of the abdominal gonad allows preoperative planning of the optimal surgical approach. Thus the surgeon can plan whether to perform staged orchiopexy, high-loop orchiopexy, microvascular autotransplantation, or a testicular ablative procedure. This preoperative planning helps the surgeon avoid unnecessary and potentially harmful dissection of the cord structures. In our opinion, such a strategy should ultimately improve testicular salvage rates.

In summary, laparoscopy permits urologists not only to diagnose testicular abnormalities but also to carry out definitive therapeutic procedures. Atrophic abdominal testes can be laparoscopically orchiectomized, thus avoiding the chance of future neoplastic transformation. The first-stage high ligation of the spermatic vessels in a planned two-stage Fowler-Stephens procedure can be performed laparoscopically using either metallic clips or the neodynium-YAG laser. Proliferation of vasal collaterals results, thus improving the chances of success of a subsequent second-stage vas-based orchiopexy.

Laparoscopic Lymphocele Marsupialization

Lymphoceles in the pelvis occur most commonly when the lymphatic channels have been transsected during retroperitoneal surgery. This complication of retroperitoneal surgery has been recognized for many years; it has occurred in 2% to 3% of pelvic lymphadenectomies for surgical staging of prostate cancer.[21] Over the last 2 decades, kidney transplant surgeons have recognized a 6% incidence of lymphocele formation resulting from unligated lymphatics adjacent to the recipient iliac vessels or in the renal allograft.[22]

When pelvic lymphoceles are small and asymptomatic, they need not be treated. However, ureteral obstruction, ipsilateral lymphedema, iliac vein compression, or pelvic discomfort may necessitate intervention for relief.

Percutaneous aseptic needle aspiration of

the lymphocele provides definitive diagnosis and often resolves the patient's problem. Frequently, however, the lymphocele recurs after a few days or weeks, and there is some risk that iatrogenic infection may be introduced by a needle or a drainage catheter, especially if multiple repeated aspirations are performed. In an effort to minimize recurrences, tetracycline or other sclerosing agents have been injected into the aspirated lymphocele, and this procedure has met with some success.

For the last 15 years, we have usually avoided multiple needle aspirations or percutaneous catheter drainage for troublesome lymphoceles and have turned instead to transperitoneal internal drainage. With the patient under general or spinal anesthesia, a window is excised in the wall of the lymphocele to bring the lymph fluid collection into continuity with the peritoneal cavity. This procedure is associated with a very low incidence of recurrence, and in our experience no serious postoperative complications have resulted.

Because the common wall separating the lymphocele and the peritoneal cavities is usually very thin and easily identified, recent technological advances in laparoscopy have made it possible to resolve lymphoceles endoscopically.[23, 24, 25] One of our patients, a 68-year-old man, developed a 15-cm lymphocele following bilateral pelvic lymphadenectomy and radical prostatectomy for carcinoma. Because of the patient's previous midline incision, the trocar was placed into the supraumbilical midline. The lymphocele was entered, two liters of lymph were drained, and the wall of the lymphocele was incised along its entire transverse dimension, effectively providing complete communication with the peritoneal cavity. The patient was discharged the following morning and returned to normal activities within the week. Follow-up sonography 3 months later revealed no reaccumulation of fluid, and the patient's abdominal symptoms were completely resolved.

Future Directions of Laparoscopy

As instrumentation continues to be developed, the potential applications for laparoscopy are growing exponentially. Urologic applications include staging of bladder, ureteral, and renal cancer. Nephrectomy, cystectomy, prostatectomy, and ileal conduit creation have already been performed in the laboratory and in small numbers of patients. Bladder augmentation and antireflux procedures appear feasible. The development of high-speed tissue morcellators and surgical sacks will allow removal of solid organs with minimal intra-abdominal contamination.

New advances in the miniaturization of endoscopes will allow even the initial puncture to be performed under direct vision. Increased applications in pediatric procedures will be possible. High resolution video cameras with improved optics will allow the surgeon to explore virtually any part of the body with reduced patient morbidity.

Despite the high costs associated with any new technology, it appears that reduction in hospitalization times, earlier return of the patient to the workplace, and the desire of patients for procedures such as these will ultimately make laparoscopy a cost-effective technique.

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Bronchogenic Carcinoma in Young Adults

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Lung cancer occurs most frequently in the sixth decade of life. It has been suggested that the incidence of bronchogenic neoplasm is increasing in the population under the age of 40. While this observation may simply reflect the general increase in lung cancer in both sexes, there is a distinct difference in the pathology and behavior of lung tumors that occur in the young.

The influence of age on the incidence and behavior of neoplastic processes has long been recognized. Bronchogenic neoplasm occurs most commonly in males after the fifth decade. When young people develop lung cancer, the tumor often exhibits a more aggressive and accelerated course than observed in the older population. Likewise, the histology of bronchogenic tumors differs in frequency of occurrence when compared to the expected distribution in the population older than 40 years.

This report profiles the presentation of a 34-year-old male who was recently diagnosed with large cell carcinoma of the lung. Based on a review of the medical literature, we review the peculiarities of primary cancer of the lung as it has affected young people.

Case Report

The patient is a 34-year-old male who presented with right pleuritic chest pain, dyspnea, and occasional cough of 2 weeks duration. His symptoms did not improve with the administration of oral erythromycin. His immediate and past health had been excellent prior to this illness. He denied exposure to tuberculosis or other infectious diseases. He had been exposed to asbestos 10 years earlier while working in the construction industry. He was not aware of other occupational exposure to toxins. He smoked one pack of cigarettes per day for 10 years. He denied any risk factors for HIV infection.

His physical examination confirmed a respiratory rate of 24 breaths per minute. The other vital signs were normal. Examination of the chest found decreased breath sounds in the right posterior base. Dullness to percussion and absent tactile fremitus were also noted in this area. The remainder of his physical examination was unremarkable.

Laboratory data included normal urinalysis and biochemical profiles. Hemogram and complete cell count with differential were unremarkable. Electrocardiogram was normal.

A pleural effusion was apparent on his admitting chest radiograph (Fig 1). A diagnostic thoracentesis was performed which was bloody in appearance and exudative by chemical analysis. No microorganisms or malignant cells were found in the pleural fluid. Computerized tomography of the thorax corroborated the presence of a large pleural effusion and demonstrated a definite pleural density and paratracheal lymphadenopathy (Fig 2). A CT guided fine needle biopsy of the pleural mass was performed. The histology was that of a large cell carcinoma of the lung.

Discussion

It is estimated that 85% of patients with bronchogenic carcinoma are between the ages of 40 and 70; less than 2% of these tumors occur in the first and second decades.[1] Approximately 4% of lung neoplasms affect patients younger than 40 years of age.[2] After the age of 40, the incidence of airway cancer increases markedly, with 13% of all lung tumors occurring between ages 40 and 45.[3] Most reports on cancer in the younger population, including this one, use the age of 40 years as the cutoff point for their observations.

The unusual features of bronchogenic carcinoma in the young were noted as early as 1954, when a series of 30 males under the age of 40 years was described.[4] In contrast to what might

be expected in older smokers, the predominant cell types differ in younger cohorts. In the population younger than 25 years of age, anaplastic small cell occurs frequently.[5,6,7] In slightly older men between 25 and 45 the predominant cell type is adenocarcinoma. In contrast, squamous cell carcinoma normally accounts for about 50% of cancers in the older age group.

The solid tumors in the young adults are commonly circumscribed and peripheral in origin (80%) rather than located in the central airways where it occurs in 60% to 80% of the older population.[4] With a peripheral location, the commonly expected presentations of bronchogenic neoplasms are not seen. Cough, hemoptysis, wheeze, and pulmonary infection which result from bronchial involvement are unusual presenting symptoms in patients under the age of 40 years. Instead, weight loss is the most common complaint. Evidence of chest wall involvement is frequent. Pain in the chest, shoulder, and/or pleural effusion are common. Many patients have additional nonspecific constitutional symptoms such as dyspnea, weakness, and fatigue. Only 2% of patients are asymptomatic with the neoplasm being found as a result of an incidental chest radiograph.[8]

The significance of cigarette smoking in young patients with lung cancer is controversial. In almost all reported studies, more than 90% of patients have been smokers who averaged about 1.6 packs per day for approximately 20 years.[8] In addition, there is now evidence that adenocarcinoma of the bronchus is, in fact, related to cigarette smoking.[9]

Other environmental carcinogens such as asbestos, chromates, radiation, and passive smoking may take on a greater profile as further studies are conducted. It has been estimated that there is no safe threshold for cigarette smoke exposure, although the effects are usually seen after the age of 45 years.[10] The carcinogenic effects of asbestos and chromates may be 15 and 11 years respectively,[4] but most authorities expect 30 to 40 years of exposure to a harmful substance for the majority of individuals to develop cancer. A genetic predisposition may allow this time interval to be shorter.

Environmental factors may act as stimuli for the transformation of respiratory mucosa to adenocarcinoma and undifferentiated tumors. It is postulated that the same stimuli may need longer to effect a change to epidermoid carcinoma. Genetic factors are most certainly at play but remain poorly defined. Finally, an acquired depressed immune surveillance system as seen in AIDS may allow the earlier occurrence of bronchogenic and other cancers.[11]

Diagnostic confusion can be avoided only by an informed clinician with a reasonable index of suspicion. In one study, two-thirds of patients



Fig 1 — Admission chest radiograph shows large pleural effusion obscuring the right lower lung fields. Mediastinum is not shifted as expected from large amount of pleural fluid.

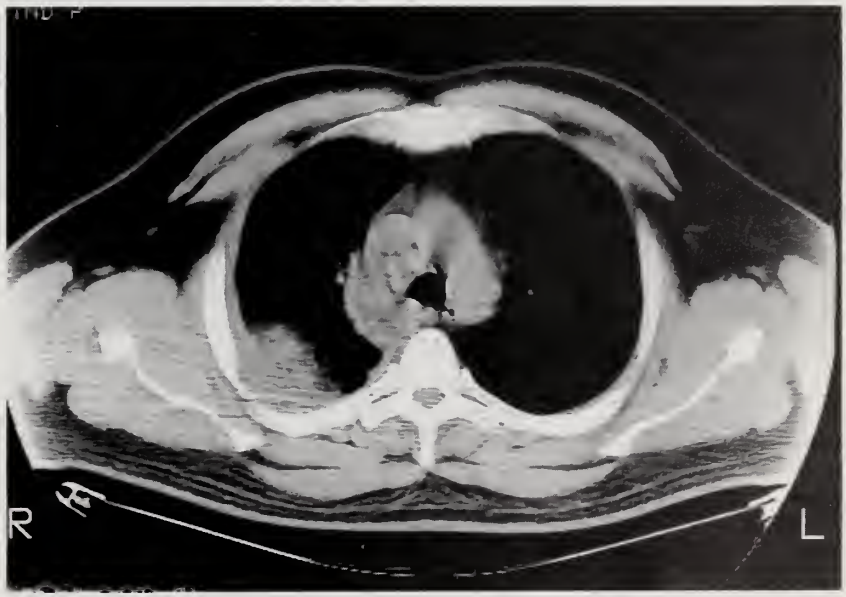


Fig 2 — Computed tomography of the chest confirms a large right sided pleural effusion, right pleural densities, and right paratracheal adenopathy.

under the age of 40 had symptoms for longer than 1 year before diagnosis.[8] The circumscribed lesion occurring in the peripheral lung zones often suggests other benign conditions such as granulomatous disease. Males outnumber females by only 2:1 or 3:1, ratios considerably closer than the 6:1 to 13:1 male-female ratios observed in the older population. The peripheral location may also decrease the yield of bronchoscopy to approximately 55%, with a range from 17% to 66%. Sputum cytology is helpful as an adjunctive study.[12]

Younger patients are generally healthy and free of co-morbid disease, factors that probably contribute to a delay in seeking medical attention. As the neoplastic process progresses, the more classical problems of airway obstruction occur, but a recurrent impression of carcinoma of the lung in younger patients is the rapidity with which the tumor progresses. More than 75% of patients under the age of 40 have stage II or stage III disease at the time of diagnosis. Distant metastases are present in 60%.[2, 13] The rapidity of tumor spread is consistent with the undifferentiated and glandular nature of these tumors.

The survival rate of young patients treated without surgery is significantly worse than that of older patients, implying a more virulent tumor behavior. In the very young with anaplastic small cell tumors, the survival averages 2.5 months.[6] The overall mean duration of survival for nonresectable young patients was reported in 1954 as 7.5 months.[4] By 1974, a 6.1 month median survival is quoted.[8] In 1980, those not resected survived an average of 27 weeks despite adjuvant therapies.[14] In most, but not all, reported series, the chances of cure or long-term survival in young patients is clearly worse than their older counterparts.[15]

The survival rate for the small number of young patients able to be resected equals that of the older population. A mean survival rate of 10.3 months is quoted for resected patients, with a similar overall 5 year survival of 10%.[12]

In summary, bronchogenic carcinoma in young adults is characterized by a lower incidence of epidermoid carcinoma and a higher incidence of adenocarcinoma and undifferentiated small cell carcinoma than found in older patients. Women constitute a greater proportion of young cancer patients, most of whom are cigarette smokers. The survival rate of nonoperable young cancer victims is much poorer than the older population, suggesting that lung cancer affecting the young is a more virulent form of lung cancer or that these younger patients have a genetic predisposition to the harmful effects of environmental carcinogens. Resection is the only available modality to arrest this disease and must be coupled with early diagnosis to have a positive impact on this population.

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Preventive Medicine: What Do Future Practitioners Really Need? Are They Getting It In Medical School?

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The purposes of our study were (1) to determine preventive medicine topics most relevant to clinical practice, and (2) to determine if medical education affects medical students' attitudes regarding preventive medicine. Our method of study was two surveys. The first survey asked practicing physicians to rank the 23 topics identified in the Healthy People 2000 *monograph and determine their usefulness in clinical practice. The second survey assessed medical students' attitudes about preventive medicine. Practitioners ranked tobacco, cancer, and diabetes as most relevant to the actual clinical practice of medicine. There were no correlations between practitioners' gender, age, or region and their rankings of topics. In terms of specialties, surgeons felt preventive medicine was less important than did family practitioners. Medical students' attitudes about preventive practices became significantly more positive as they progressed through medical school. Survey scores also improved significantly in second year students after their preventive medicine course. Students planning to be surgeons were less positive about preventive medicine. There is a continuing need for prevention education in medical school curricula, especially about tobacco, cancer, diabetes, and nutrition. Epidemiology and disease reporting might best be presented as "how to read the literature."*

Background

The rising cost of caring for patients with preventable diseases has led to increased emphasis on preventing disease and promoting health among health care providers, patients, and third party payors. Consequently, there is an increased awareness of the need for comprehensive, effective, and relevant preventive medicine education in medical school curricula. Due to concern expressed by medical students at the University of Kentucky about the relevance of their second year course in Preventive Medicine, we wondered what preventive medicine information was most useful to the practitioner. We also wondered whether medical school education affected medical students' knowledge or attitudes about preventive practices.

We addressed these questions with surveys of two different populations: practicing physicians (the "gold standard") and medical students at the University of Kentucky at several points in time.

Methods

Practitioner Survey

In an effort to learn what information is most useful to the practitioner, we chose a random sample of 200 Kentucky physicians from the roster of licensed physicians in Kentucky. We chose to sample all licensed practicing physicians because medical students have the potential to enter any field at the time they are taking Preventive Medicine; we needed to know the perceived need for preventive training among all kinds of practitioners, not just those practicing preventive medicine or primary care.

Personalized cover letters accompanied a one page questionnaire to be completed on an Optiscan computer sheet. A self-addressed, stamped envelope was enclosed. Respondents were asked to darken a circle on a Likert scale of zero to nine, corresponding to their belief about the relevance of each topic, with zero being not relevant and nine being essential to their practice.

Topics to be evaluated for relevance and usefulness were chosen from *Healthy People 2000: National Health Promotion and Disease Prevention Objectives.*[1] This document is the product of a national effort involving 22 expert working

On the enclosed bubble sheet, please fill in the number corresponding to the relevance of the following topics to your clinical practice, with 0 being not relevant and 9 being essential to your practice:

1. Physical Activity and Fitness
2. Nutrition
3. Tobacco
4. Alcohol and Other Drugs
5. Family Planning
6. Mental Health and Mental Disorders
7. Violent and Abusive Behavior
8. Educational and Community-Based Programs
9. Unintentional Injuries
10. Occupational Safety and Health
11. Environmental Health
12. Food and Drug Safety
13. Oral Health
14. Maternal and Infant Health
15. Heart Disease and Stroke
16. Cancer
17. Diabetes and Chronic Disabling Conditions
18. HIV Infection
19. Sexually Transmitted Diseases
20. Immunization and Infectious Diseases
21. Clinical Preventive Services
22. Disease Reporting
23. Epidemiology

Demographic information:

24. WHAT IS YOUR SEX? (Please fill in 0 for male, 1 for female)
25. IS YOUR PRACTICE IN A RURAL OR URBAN SETTING? (Please fill in 0 for rural, 1 for urban)
26. WHAT IS YOUR AGE?

20-25 (Please fill in 0)	46-50 (Please fill in 5)
26-30 (Please fill in 1)	51-55 (Please fill in 6)
31-35 (Please fill in 2)	56-60 (Please fill in 7)
36-40 (Please fill in 3)	61-65 (Please fill in 8)
41-45 (Please fill in 4)	65+ (Please fill in 9)

27. DO YOU CONSIDER YOURSELF A PRIMARY PHYSICIAN? (Please fill in 0 for no, 1 for yes)
28. WHAT IS YOUR SPECIALTY?

Family Practice	(Please fill in 0)	Ophthalmology	(Please fill in 5)
Medicine/Medicine Subspecialty	(Please fill in 1)	Psychiatry	(Please fill in 6)
Pediatrics	(Please fill in 2)	Anesthesiology	(Please fill in 7)
Obstetrics/Gynecology	(Please fill in 3)	Radiology	(Please fill in 8)
General Surgery/Surgical Subspecialty	(Please fill in 4)	Other	(Please fill in 9)

Thank you very, very much for your help with this. Please return in the self-addressed, stamped envelope provided, or mail to:

Barbara Phillips, MD
Division of Pulmonary and Critical Care Medicine
University of Kentucky Chandler Medical Center
800 Rose Street, MN579
Lexington, Kentucky 40536

Questionnaire

groups, about 300 national organizations, all state health departments, and the Institute of Medicine of the National Academy of Sciences, working with the US Public Health Service. It represents a distillation of the preventive topics or areas of intervention of most interest to the country's leading experts in the field.

At first mailing, 92 questionnaires were returned (46% response rate). A follow-up mailing, approximately 3 weeks after the first mailing, reminded the target group of the importance of the survey, and again requested them to complete the survey and return it. A total of 107 surveys (54%) were returned. This represents about 1.5% of Kentucky's licensed physicians.

To determine the perceived importance of a number of preventive medicine topics among selected physicians practicing in Kentucky, a number of statistical analyses were performed on the questionnaire data. It was anticipated that the analyses would demonstrate: an ordering of prevention topics by importance to physicians; possible relationships between the importance of prevention topics and physician age, gender, and practice location; a relationship between the overall importance rating of topics and the respondent's medical specialty; and possible relationships that might exist between prevention topics themselves.

Mean scores were computed for each importance topic and for the overall prevention score. Pearson product-moment correlations were com-

puted to demonstrate relationships between the overall mean of prevention topics and the respondent characteristics of age, practice location, and gender. The ANOVA technique was selected to test for differences in the means of importance scores from respondents classified as family practice, medicine, and general surgery. Post hoc tests, including Tukey-Kramer and Student's t, were then used to determine the source of the significance. A matrix of Pearson product-moment correlations was produced to describe the strength of suspected relationships between various prevention topics across respondents. A principal components factor analysis, with varimax rotation, was used to compute amount of variance in the total importance model attributable to the strongest topic-topic relationships.

Student Survey

For the study of effects of medical school curriculum on students' attitudes about prevention, students at the University of Kentucky were administered a survey over a 2 year period from 1989 to 1991 as part of our participation in the Preventive Pulmonary Academic Award (PPAA). The survey measure is named the Pulmonary Disease Prevention Survey (PDPS) and was developed by investigators at the University of North Carolina.[2] The PDPS was developed with the intent of producing a valid and reliable measure of attitude toward pulmonary disease prevention. The initial group of items were written by a small group of PPAA awardees. Ten questions were written for each of six categories deemed relevant to attitudes toward pulmonary disease prevention:

1. Skill and knowledge needed by physicians
2. Efficacy/effectiveness of physicians
3. Preventability of lung disease
4. Incentives for physicians
5. Other's expectations of preventive services
6. Responsibility of physicians

Elimination of seemingly duplicate items reduced the initial base to 42 items. The initial item pool was then reviewed by experts, the Lung Disease Prevention Task Force, which is a group of physicians and behavioral scientists assembled by the NHLBI of the NIH. Their review resulted in the deletion of seven items due to poor wording, impropriety, or redundancy, leaving 35 items in the pool. Some of these were edited for clarity.

This survey was distributed to a pilot sample of 110 medical students. The internal consistency reliability analysis for this group of respondents resulted in an alpha coefficient of 0.77. Since that time, the survey has been completed by 2,691 students and the alpha coefficient for this sample was 0.83. A factor analysis of this same group of respondents revealed that the instrument is unidimensional.

A test-retest reliability was also conducted for a group of second year students at UNC. They completed the questionnaire once in the first semester and then again 18 weeks later (51 students were matched using social security numbers). The test-retest reliability was 0.57.

The 35 item questionnaire asked students to rate on a 1-5 Likert scale whether they agreed or disagreed with statements regarding preventive medical practice.

For approximately one half of the statements, agreement indicated a positive attitude toward preventive practices as judged by the developers of the questionnaire. For the remaining items, disagreement indicated a positive attitude, and responses were reversed for scoring. Thus, the total score reflected the level of "positivity" toward prevention.

The "best" possible score was 175. The PDPS generated a mean attitude score of 127.98, with a standard deviation of 11.63, from a verification study of 2,691 medical students from 13 US medical schools. Surveys were administered by the PPAA awardee, generally during in-class administrations at several points during the students' medical education. Approval for administration of the survey was obtained from the institution's IRB. Students were advised that participation was both voluntary and anonymous. Results presented here pertain only to data from University of Kentucky students.

Data Analysis of Student Survey

Data analysis on the survey of medical students was performed using ANOVA for all comparisons. Tukey's Standardized Range Test was used when post hoc tests were necessary to identify sources of significant difference.

Results

Physician Survey

Of the respondents to the questionnaire, 72 (67%) classified themselves as urban practitioners. Our sample was fairly equally divided between physicians who considered themselves to be primary

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PULMONARY DISEASE PREVENTION SURVEY

Please report how much you agree or disagree with each of the following statements. Using the scale to the right, fill in **ONLY ONE BOX** to record your judgement.

	STRONGLY DISAGREE	DISAGREE	UNCERTAIN	AGREE	STRONGLY AGREE
1. Scientific data support smoking cessation as an effective preventive measure even after many years of smoking.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
2. Smoking cessation counseling is a necessary part of routine care by all physicians regardless of specialty.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
3. Prevention of occupational lung disease should mainly be the concern of specialists in occupational medicine.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
4. Most of my patients will expect health promotion counseling to be included as part of routine care.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
5. I should **NOT** spend time providing health promotion counseling if this reduces the number of patients I see.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
6. It's **NOT** worth the time to counsel older patients to stop smoking.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
7. Preventive medicine should be a required subject in medical school even if this reduces the time devoted to other topics.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
8. I should use part of each patient encounter to promote lifestyle changes which may prevent disease.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
9. My advice to stop smoking will be sufficient to get some patients to quit.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
10. If given instructions, most asthmatics can make medication adjustments on their own as symptoms vary.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
11. I should spend time on smoking cessation counseling even if this reduces time available for diagnosis and treatment.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
12. I will be negligent if I do **NOT** counsel patients about behaviors which might contribute to future illness.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
13. Individual physicians can have little impact on prevention of environmental and work-related respiratory disease.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
14. Counseling for prevention of lung disease is as important as prescribing medication.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
15. If patients do not express an interest in making lifestyle changes, I am **NOT** obligated to counsel them to change their behavior.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
16. Smoking cessation counseling will be an effective use of my time as a physician.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
17. Most lung diseases are **NOT** preventable except those related to smoking.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
18. Health professionals other than physicians should provide most counseling for prevention of lung disease.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
19. Physicians are **NOT** adequately paid for time spent counseling patients about smoking.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
20. My patient education efforts will be effective for increasing compliance with recommended lifestyle changes.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
21. Most chronic lung diseases are **NOT** preventable by changes in behavior.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
22. Prevention of smoking related diseases is possible only if healthy lifestyles are established during childhood.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
23. Counseling patients about smoking is **NOT** all that important compared to most other aspects of medical care.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
24. Trained health educators, not physicians, should provide patient education for prevention of lung disease.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
25. In addition to caring for individual patients, I have an obligation to improve the health of the community.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
26. Counseling skills for influencing patients to adopt healthier lifestyles will be as important to my effectiveness as my treatment skills.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐

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	STRONGLY DISAGREE	DISAGREE	UNCERTAIN	AGREE	STRONGLY AGREE
27. Professional medical societies encourage the incorporation of services for prevention of lung disease into routine care.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
28. For most patients health education does little to promote their adherence to a healthy lifestyle.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
29. I will be less effective than professional counselors in getting patients to quit smoking.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
30. Patients without symptoms will rarely change their behavior on the basis of my advice.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
31. All physicians, regardless of specialty, should perform tuberculin testing on high risk patients.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
32. Knowledge about prevention will be as important to my effectiveness as knowledge about treatment.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
33. Curing an illness is more gratifying than preventing one.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
34. Most patients try to change their lifestyles if I advise them to do so.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐
35. It is important that all patients with chronic lung disease receive yearly influenza vaccinations.	⊏1⊐	⊏2⊐	⊏3⊐	⊏4⊐	⊏5⊐

BACKGROUND DATA

36. AGE

⊏0⊐	⊏0⊐
⊏1⊐	⊏1⊐
⊏2⊐	⊏2⊐
⊏3⊐	⊏3⊐
⊏4⊐	⊏4⊐
⊏5⊐	⊏5⊐
⊏6⊐	⊏6⊐
⊏7⊐	⊏7⊐
⊏8⊐	⊏8⊐
⊏9⊐	⊏9⊐

37. GENDER

MALE ⊏ ⊐
FEMALE ⊏ ⊐

38. CURRENT STUDENT STATUS (ONE ONLY)

1st Year ⊏ ⊐ 3rd Year ⊏ ⊐
2nd Year ⊏ ⊐ 4th Year ⊏ ⊐

39. PLANNED SPECIALTY (one only)

⊏ ⊐MEDICINE ⊏ ⊐NEUROLOGY
⊏ ⊐SURGERY ⊏ ⊐OTHER (SPECIFY) _____
⊏ ⊐PEDIATRICS
⊏ ⊐FAMILY MEDICINE ⊏ ⊐UNCERTAIN
⊏ ⊐OB/GYN

40. HAVE YOU SMOKED 100 CIGARETTES OR MORE IN YOUR ENTIRE LIFE? ⊏Y⊐ ⊏N⊐

41. DO YOU SMOKE CIGARETTES REGULARLY NOW? ⊏Y⊐ ⊏N⊐

44. LOCATION

⊏A⊐	⊏A⊐	⊏A⊐
⊏B⊐	⊏B⊐	⊏B⊐
⊏C⊐	⊏C⊐	⊏C⊐
⊏D⊐	⊏D⊐	⊏D⊐
⊏E⊐	⊏E⊐	⊏E⊐
⊏F⊐	⊏F⊐	⊏F⊐
⊏G⊐	⊏G⊐	⊏G⊐
⊏H⊐	⊏H⊐	⊏H⊐
⊏I⊐	⊏I⊐	⊏I⊐
⊏J⊐	⊏J⊐	⊏J⊐
⊏K⊐	⊏K⊐	⊏K⊐
⊏L⊐	⊏L⊐	⊏L⊐
⊏M⊐	⊏M⊐	⊏M⊐
⊏N⊐	⊏N⊐	⊏N⊐
⊏O⊐	⊏O⊐	⊏O⊐
⊏P⊐	⊏P⊐	⊏P⊐
⊏Q⊐	⊏Q⊐	⊏Q⊐
⊏R⊐	⊏R⊐	⊏R⊐
⊏S⊐	⊏S⊐	⊏S⊐
⊏T⊐	⊏T⊐	⊏T⊐
⊏U⊐	⊏U⊐	⊏U⊐
⊏V⊐	⊏V⊐	⊏V⊐
⊏W⊐	⊏W⊐	⊏W⊐
⊏X⊐	⊏X⊐	⊏X⊐
⊏Y⊐	⊏Y⊐	⊏Y⊐
⊏Z⊐	⊏Z⊐	⊏Z⊐

42. SOCIAL SECURITY NUMBER

⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐
⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐
⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐
⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐
⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐
⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐
⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐	⊏6⊐
⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐	⊏7⊐
⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐	⊏8⊐
⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐	⊏9⊐

43. DATE

MO		DAY		YR	
⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐	⊏0⊐
⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐	⊏1⊐
⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐	⊏2⊐
⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐	⊏3⊐
⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐	⊏4⊐
⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐	⊏5⊐
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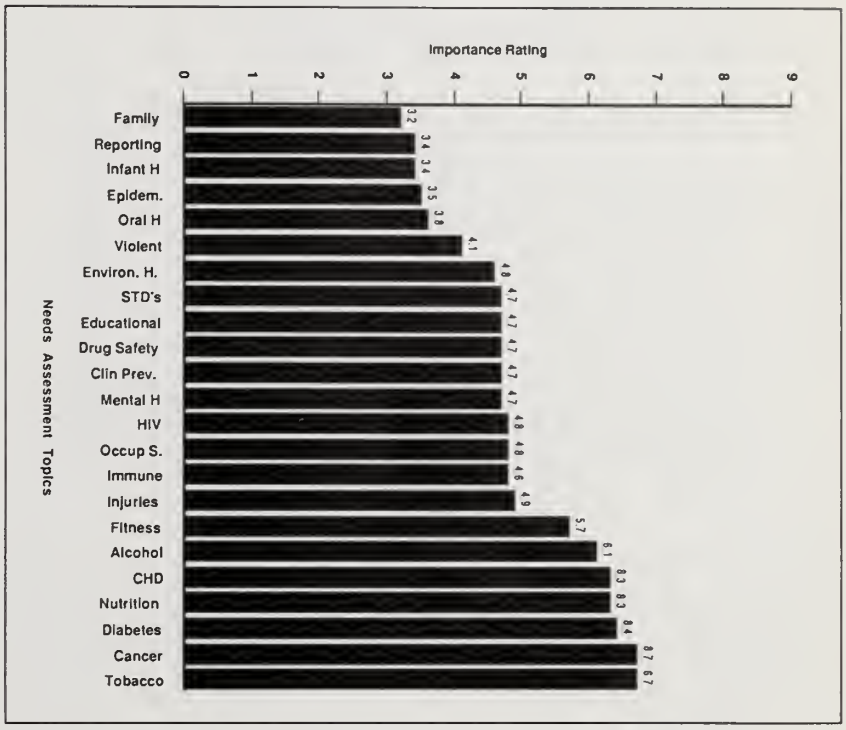
care physicians (51%) and those who did not (49%). The median age range of our practitioners was approximately 40 years. Twenty-three percent were family practitioners, 17% "other," 16% surgery, and 15% medicine. Fourteen percent of the respondents were women and 86% were men.

Relative ranking of the raw scores on the Likert scale can be seen in Fig 1. Our respondents rated tobacco, cancer, diabetes, nutrition, coronary heart disease, and alcohol as the most relevant topics to their clinical practice. Topics related to family planning, infant health, epidemiology, and oral health were rated as least important by responding physicians.

The Pearson product-moment correlations between the overall mean and respondents' age (−0.24), gender (+0.15), and practice location (−0.03) were not significant, indicating that these variables did not correlate in the mean prevention score.

The one-way analysis of variance showed a significant main effect ($F = 4.05$, $p < 0.05$), confirming a model in which medical specialty accounts for a major source of the variance in respondents' prevention importance scores. Subsequent post hoc tests revealed a significant difference ($t = 2.41$, $p < 0.05$) between the prevention importance responses of family practice physicians and those of general surgeons; surgeons had lower total scores for the importance of prevention.

The matrix of Pearson product-moment correlations presented a number of interesting correlational relationships between prevention importance rating items. Factor analysis assisted in determining the strongest (Eigenvalue > 1.0) of these relationships. The first factor contained items relating to family planning, infant health, HIV, sexually transmitted disease, and the immune system. This factor alone accounted for 36% of the total variance in prevention importance scores. The second factor accounted for 8% and contained items relating to tobacco, coronary heart disease, cancer, and diabetes. The third factor, accounting for 7.6% of the variance, included unintentional injuries, occupational safety, and environmental health. The fourth factor, accounting for 5.8%, contained alcohol, family planning, mental health, and violent/abusive behavior. The fifth factor, accounting for 5.1% of the variance, included oral health, reporting, and epidemiology. The final factor, accounting for 4.1%, included fitness, nutrition, and clinical preventive services.



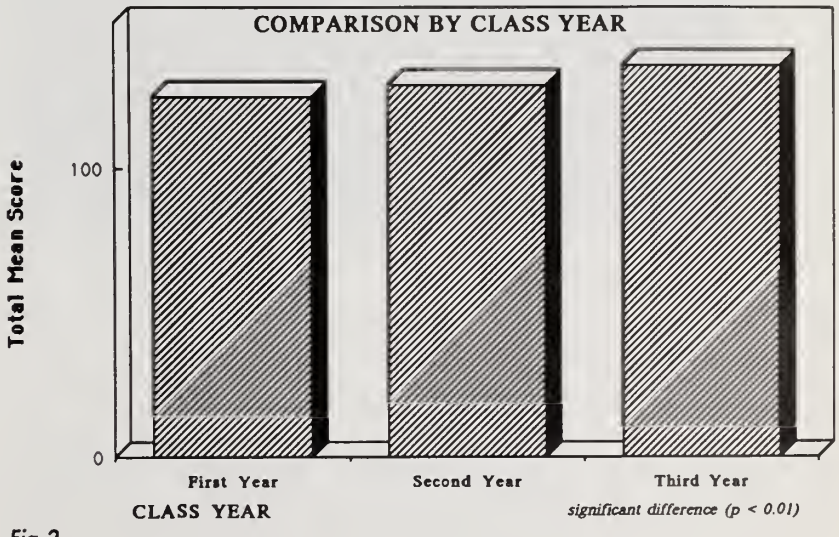
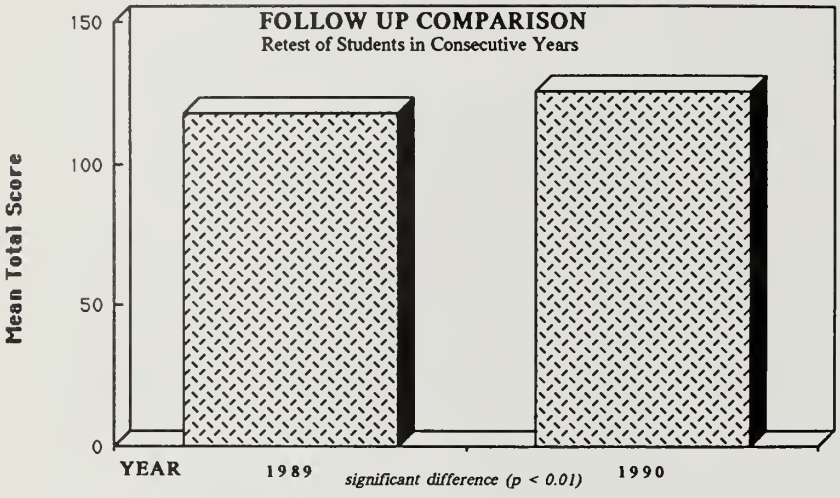


Fig 2

Medical Student Survey

Fig 2 is a cross sectional comparison of the first, second, and third year classes in the 1990-91



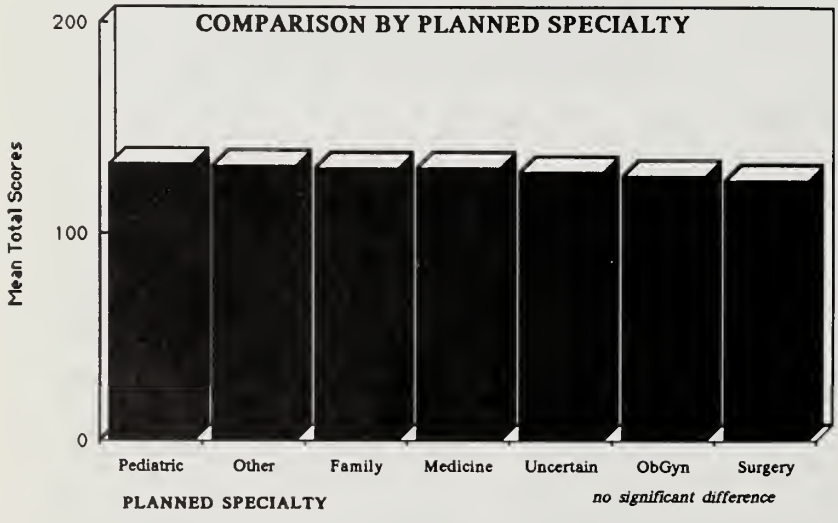


Fig 4

school year. There was a significant difference between class years for the University of Kentucky students, who showed a significantly more positive attitude with each successive year ($n = 212$, $p < 0.05$).

Fig 3 depicts four follow-up analyses of data collected from students in the 1989-90 school year and data collected from those same students in the 1990-91 school year. Significant differences were found at the University of Kentucky in those students who were followed longitudinally ($n = 157$, $p < 0.01$).

Because of the significant increasing positivity of the attitudes about prevention at the University of Kentucky, we selectively looked at results from two administrations of the survey during the second year. The first administration was at the beginning of their Preventive Medicine course; a second administration was at the end. The analysis was done on the 24 students who provided their social security numbers on both administrations. The students' attitudes were significantly improved between the first and second administrations ($p < 0.05$).

Fig 4 compares the mean total scores for respondents, broken down by their planned specialty. Unlike other data presented from this survey, these data by specialty were collected at 12 institutions (University of Alabama, Cleveland College of Medicine, University of Kentucky, Medical College of Pennsylvania, Yale University, University of Medicine and Dentistry of New Jersey, Temple University, University of Pittsburgh, University of California at San Diego, University of Washington, University of North Carolina at Chapel Hill, New York Medical College), totaling 2,544 students. The number of students in each specialty ranged from 51 to 874. Mean total scores for each of the eight specialties are listed in descending order. Mean total scores ranged from 124.93 to 132.22. Students planning to go into pediatrics or family practice had the most positive attitudes. Those planning to go into OB/GYN or Surgery showed significantly more negative attitudes than the other six specialities shown ($p < 0.01$).

Discussion

To our knowledge, this is the first and only survey about the relevance of various preventive medicine/public health topics to the practices of clinicians in the state of Kentucky. As such, it may be only applicable to Kentucky physicians, as our state's culture is unique and is significantly influenced by tobacco, poverty, Appalachia, coal mining, and a weak education system.

However, we think the findings are enlightening and some may be applicable to other states or institutions of learning. Our physician respondents clearly identified topics of extreme relevance: tobacco, cancer, diabetes, and nutrition. Smoking cessation and tobacco use counseling have been identified in other surveys of physicians as the extremely important physician tools.[3,4] These topics need to be emphasized in

medical schools and in continuing medical education. Additionally, our physician respondents singled out topics that they considered to be less germane: epidemiology, infant health, disease reporting, and family planning. We believe our sample is representative of physicians in practice in Kentucky, but the relatively low percentages of obstetricians/gynecologists (approximately 5%) and pediatricians (approximately 4%) in our sample may have contributed to the fairly low scores for family planning and infant health.

In the survey of practicing clinicians, we failed to identify differences in emphasis on preventive topics according to age, rural versus urban practice, or gender. Although more recent curriculum places more emphasis on preventive medicine, it is likely that the practicing physician who has been exposed to the consequences of illnesses and is aware of the differences that prevention can make will have acquired "on the job" first-hand experience with the importance of preventive medicine in clinical practice. We were extremely interested to note a striking difference in emphasis based on practice specialty. Surgeons responding to our survey were much less interested in the clinical preventive medicine and public health topics than were family practitioners or pediatricians. This finding has been reported by others.[5] Because of the data from the medical student survey, we believe that these differences in attitudes exist prior to entry to medical school.

The factor analyses of physicians identified "five interesting clusters of disease/topic-relatedness." That our respondents grouped family planning and infant health together makes sense; HIV, sexually transmitted disease, and the immune system were also linked to this cluster. We wonder if this indicates a belief that family planning also prevents the transmission of sexually transmitted diseases, or reflects a concern about transmission of STDs to infants in utero, or represents some other association.

Interestingly, clinicians responding to the survey linked tobacco with coronary heart disease and cancer, which makes sense, as well as diabetes, which is less obviously relevant. Alcohol was not linked with disease but with behavioral factors, including family planning, mental health, unintentional injuries, and violent/abusive behavior. Fitness, nutrition, and clinical preventive services were lumped together and may relate to the concept of wellness now promoted in the lay press, as well as the medical literature.

Data from the University of Kentucky indicate that medical education in general and preventive medicine education in particular can improve the knowledge and attitudes of medical students about preventive medicine.

Taken together, our survey would indicate a continuing need for education about tobacco abuse and control, cancer, diabetes, and nutrition in medical school and in continuing medical education. Surgeons and surgeons-to-be may represent a subgroup of practitioners who may need extra attention or effort to reverse preexisting attitudes about prevention. Epidemiology and disease reporting are not felt to be as relevant by the practicing physician and perhaps might best be presented as "how to read the medical literature" by those trying to educate future or current practitioners.

ACKNOWLEDGEMENTS: Supported by a Preventive Pulmonary Academic Award, NIH, and by the Dean's Scholarship Fund, University of Kentucky.

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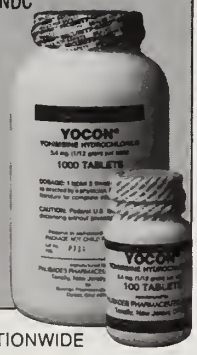
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Cholera Revisited

"Grow up, American medicine, about the shrinking world, where hours separate us from the dangers abroad."

Many passengers on an airplane bound to Los Angeles from South America developed cholera. Most patients recovered with fluid replacement and some anti-diarrhea medication. However, some patients became very seriously ill, with a few deaths. No patients were immunosuppressed or otherwise likely to be affected. Many required hospitalization, and many worked only after many lost days.

This episode dramatically demonstrates that cholera devastates its victims. Spreading rapidly among people in close proximity, not requiring intimate contact, and causing significant morbidity in virtually every patient, cholera resurfaces as another scourge of the late 20th century. Newspapers and other media told us of numerous cholera epidemics occurring in South America, India, Africa, and the Far East. Distance and foreigners insulated us to some degree from aggressively pursuing this growing menace. Some of us took off for these lands, ready to help with the problem. The United Nations actively recruited money and personnel to confront the logarithmically increasing problem. However, very few of us challenged the thought that cholera would not, to any significant degree, invade our shores. Generally, good health, respectable sanitation, and sewage treatment promoted resistance to cholera, if not ultimate protection.

Such an invasion from cholera, transported quickly by our trans-oceanic and -continent vehicles, penetrated our bubble of security. Now, riding on the airplane, crossing the Mexican border with our car, traveling the rail lines in other countries — all exposures could be indicted and suspected. "Don't drink the water" becomes not only the warning, but the tip of the iceberg. Grow up, American medicine, about the shrinking world, where hours separate us from the dangers abroad. Diseases that hitherto were the province of others, are knocking at our doors, and threaten to hop in bed with us!!!

What in the past has been a benevolent act by us to help others with diseases such as cholera, is becoming a national priority. Public health measures, attention to traveling history, early symptomatic care, and monitoring of contacts can modify the effect of these diseases. Be aware that problems of developing countries are germane to us, and must be one of our priorities to resolve.

Stephen Z. Smith, MD

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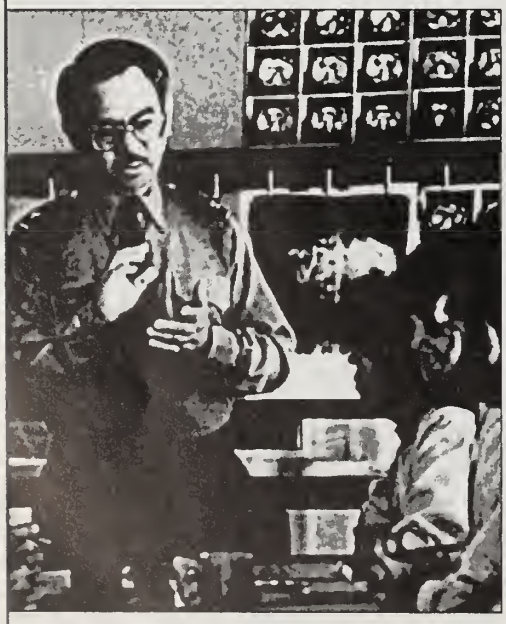


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Doctors' Day

"We recognize your sacrifices and appreciate all that you do to provide quality health care for citizens of the Commonwealth."

In the spring of 1991, President George Bush proclaimed March 30 as National Doctors' Day. This was the culmination of much work by physician spouses from across the country, spearheaded by the Southern Medical Association Auxiliary.

In 1933, Eudora B. Almond suggested that her medical auxiliary in Barrow County, Georgia, set aside a day to honor physicians and their work. March 30 was selected since it was the anniversary of the day that Dr Crawford W. Long, a Georgia physician, first used ether anesthesia during surgery in 1832.

On or about March 30, auxiliaries, hospitals, and individuals across the Commonwealth will show their appreciation of their physicians. Breakfasts and dinners will be held; service awards will be given; contributions will be made to libraries, free medical clinics, and AMA-ERF; blood drives will be held; and awards will be given to outstanding science students. This and more will be done in honor of physicians.

We in the Auxiliary to the Kentucky Medical Association are in a unique position to understand the sacrifices made by our physician spouses. We recognize your sacrifices and appreciate all that you do to provide quality health care for citizens of the Commonwealth.

You are indeed — WORKING TODAY FOR A BETTER TOMORROW.

Beryl Dodds

AKMA President



KMA Board of Trustees — December Meeting





Left: Commissioner for Health Services Rice Leach, MD, addressed the Board about his department's initiatives. Above: President William B. Monnig, MD, was presented a replica of the October Journal *cover bearing his picture, by KMA Executive Vice President Robert G. Cox.*

Convening in a regular session, the KMA Board of Trustees met on December 17, 1992. The Board members heard reports of the President, the Secretary-Treasurer, the Senior Delegate to AMA, the Vice Dean of the University of Louisville School of Medicine, the Commissioner for Health Services, Chairman of the KEMPAC Board of Directors, and Chairman of the KMIC Board of Directors. It was noted that the Board of the KMA and the Kentucky Medical Insurance Company had met in joint session the previous day to discuss matters of mutual interest.

The Director of the Medicare Part B Program, James B. Holloway, Jr, MD, also updated the Board members regarding activities in the Medicare Program. Representatives of Kentucky Blue Cross and Blue Shield made a presentation regarding the KMA-endorsed BCBS plan for the membership.

Detailed reports were given concerning the activities of the Committees on National and State Legislative Activities, which included plans for the Special Session of the Kentucky General Assembly in 1993. The Board members held a lengthy discussion about health care reform, to be considered by the Special Session, and took note of policy which had been adopted by the 1992 House of Delegates in this regard.

The Board directed that, pending permission of the Kentucky Supreme Court, an amicus curiae brief be filed in a "wrongful life" suit. Appointments were made to the KMIC Board Election Nominating Committee, and the report of the Membership Committee was accepted, which noted KMA has experienced the highest percentage and number increase in membership in more than 22 years. The Board members approved a policy on HIV/HBV infected physicians, adopted a modified CME Mission Statement, and approved names for submission to the Cabinet for Human Resources for service on a Drug Utilization Review Committee.

The Board members also approved updating a brochure on child abuse that had been developed several years ago, and endorsed action taken to purchase a building lot in the Hurstbourne Green development in Louisville for a future headquarters for KMA and the Kentucky Medical Insurance Company. A report on cost-cutting measures to be implemented in the *Journal of the Kentucky Medical Association* was accepted, and action taken to implement directives of the 1991 House of Delegates was also endorsed.

The next meeting of the Board was scheduled for April 14-15, 1993, at the Hyatt Regency Hotel in Louisville.

KMA



AKMA President Beryl Dodds presented a report highlighting the accomplishments of the Health Careers Fund Committee.



The Board heard a report from Chairman of the KMIC Board of Directors Richard F. Hench, MD.





Five New Officers Elected to KMA Board of Trustees

During the 1992 KMA annual House of Delegates meeting held in Louisville, five new officers were elected to serve on the Board of Trustees. KMA congratulates the following members on their election and thanks them for their valuable leadership.

Harry W. Carloss, Jr, MD, was elected to serve a three-year term as 1st District Trustee.

An internist, Dr Carloss practices in Paducah. He attended school in his native Kentucky, earning a BS from the University of Kentucky in 1976 and an MD from the University of Louisville in 1975. His subsequent education included an internship in 1975-77 and a residency in 1976-78 at the University of Louisville Affiliated Hospitals, where he served as chief medicine resident in 1977-78. He then spent two years as a research fellow at the Scripps Clinic and Research Foundation in the division of hematology/oncology, one year of which he served as chief hematology fellow and chief fellow.

Active in KMA since 1981, Dr Carloss is a member of the Cancer Committee, Trends Committee, and Kentucky Physicians Care Operating Committee. He has served as a KMA Delegate for McCracken County since 1987. Nationally, he serves on the AMA Advisory Committee to HCFA. Other professional associations include the American Society of Internal Medicine, American Society of Hematology, American Society of Clinical Oncology, and as a fellow of the American College of Physicians and the Royal Society of Medicine. Dr Carloss is also extensively involved in civic and community activities.

In addition to being an attending physician at Lourdes and Western Baptist Hospitals in Paducah, Dr Carloss is a consulting physician at Mayfield Community Hospital and an assistant professor in clinical medicine at the University of Louisville.

Dr Carloss, 43, and his wife, Barbara, reside in Paducah. They have three children.



William H. Klompus, MD, a Madisonville urologist, was elected to serve a three-year term as 3rd District Trustee.

A member of KMA since 1967, Dr Klompus has been a Delegate from Hopkins County to the KMA since 1981 and has served on several committees. He has been active in leadership roles in the past, including service as President of the Kentucky Urological Association and the Hopkins County Medical Society. Other professional memberships include American College of Surgeons, International College of Surgeons, American Urologic Association, Southeastern Section American Urologic Association, and life membership in the Southern Medical Association.

A native of New Jersey, Dr Klompus, 59, earned his undergraduate degree in 1955 from Dickinson College in Carlisle, Pennsylvania, and his medical degree from New York Medical College Metropolitan Medical Center, Valhalla, in 1959. He fulfilled an internship and a general surgery residency at Harrisburg Polyclinic Hospital, Harrisburg, Pennsylvania, in 1959-61, followed by a urology residency at the University of Louisville Hospitals in 1963-66.

A staff member of the Regional Medical Center and Trover Clinic in Madisonville, Dr Klompus is also on the courtesy staff of Jennie Stuart Medical Center, Hopkinsville, and Humana Hospital Suburban and Methodist Evangelical Hospital, Louisville. He holds a faculty appointment at the University of Louisville, where he is a clinical professor of urological surgery.

Dr Klompus and his wife, Joan, have three children and live in Madisonville.



Salem M. George, MD, a family practitioner in Lebanon, was elected to serve a three-year term as 4th District Trustee.

Dr George has been an involved member of KMA since 1961, having served several years as a Delegate for Marion County and on the KEMPAC Board of Trustees. He is an active member of the Marion-Washington County Medical Society, Kentucky Academy of Family Physicians, and a fellow of the American Academy of Family Physicians.

Long active in civic and community activities, Dr George was a member of the Marion County Health Board for more than 25 years and served as a Lebanon City Councilman for several years. In 1966, he was selected Outstanding Young Man for the Jaycees of Kentucky, and in 1981 he was named the Lebanon-Marion County Chamber of Commerce Outstanding Citizen.

Dr George completed his undergraduate studies at Notre Dame and the University of Louisville in 1955, and was awarded a medical degree from the University of Louisville School of Medicine in 1959. The former St Joseph's Infirmary in Louisville was the site of his internship in 1959-60.

He is on the staff of Spring View Hospital, where he has served as chairman of the board and chief of staff.

Dr George and his wife, Eva, have six children and make their home in Lebanon.



Scott B. Scutchfield, MD, an orthopedic surgeon in Danville, was elected to serve a three-year term as 12th District Trustee.

Dr Scutchfield has been an active KMA member since 1982 and brings several years of experience to his office. His service includes Delegate from Boyle County since 1982; 12th District Alternate Trustee during 1986-92; and as a member of the State Legislative and Membership Committees. He is a past president of the Boyle County Medical Society and the Kentucky Orthopedic Society. Other professional memberships include Southern Orthopedic Association, Southern Medical Society, and Christian Medical-Dental Society. Dr Scutchfield is a diplomat of the National Board of Medical Examiners and the American Board of Orthopedic Surgery, and a member of the Board of Councilors, American Academy of Orthopaedic Surgeons, representing Kentucky.

A 1970 graduate of Morehead State University, Dr Scutchfield earned his MD from the University of Kentucky College of Medicine in 1975, followed by surgical internship and orthopedic residency training at the Medical University of South Carolina in Charleston during the period 1975-79. He was chief resident in orthopedic surgery in 1979-80.

He has privileges at Ephraim McDowell Memorial Hospital in Danville, where he served as chief of surgery in 1987.

Dr Scutchfield, 48, and his wife, Bunny, have two children and reside in Danville.



E. D. Roberts, MD, a family practitioner in Pikeville, was elected to serve a three-year term as 14th District Trustee.

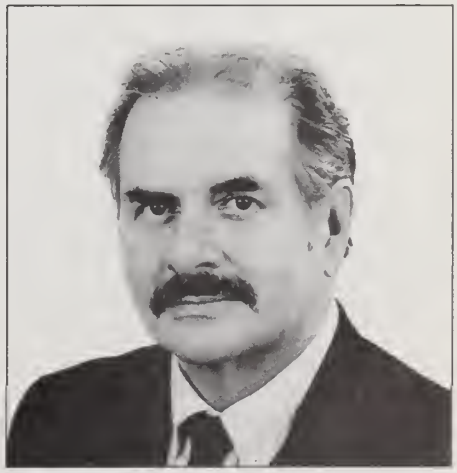
An active member of KMA for several years, Dr Roberts, 55, has served as a Delegate to KMA for Pike County.

He is a native of Pikeville and a 1959 graduate of the University of Kentucky. After being awarded a medical degree from the University of Louisville School of Medicine in 1963, Dr Roberts completed an internship in 1963-64 at Floyd Memorial Hospital in Rome, Georgia. He subsequently graduated from the Naval School of Aerospace Medicine in December of 1964 and served as a naval flight surgeon from 1964 to 1968. He currently serves as a senior examiner for the Federal Aeronautics Administration.

Dr Roberts is affiliated with Pikeville Methodist Hospital, where he serves as physician director of emergency services, director of ACLS instructor team, and assistant director of the paramedic school. He is active in several civic and community efforts.

An adjutant professor of anatomy, pathology, and immunology at Pikeville College, Dr Roberts is also an AIDS lecturer in Kentucky and West Virginia.

He and his wife, Cathy, live in Pikeville. They have five sons.





S. Randolph Scheen, MD Honored by KMA Board

For his 26 years of distinguished service to the Kentucky Medical Association, S. Randolph Scheen, MD, of Louisville, was honored by the Board of Trustees at the December Board meeting. President William B. Monnig, MD, made the following comments as he unveiled a portrait of Dr Scheen. "This painting will hang in the halls of KMA. It will remain for all times and express the deep respect and high esteem that we as members of the Board of Trustees, members, and staff of the Association have for you."

In 1967, Dr Scheen was elected Secretary of the Kentucky Medical Association. He served in that office, later combined into Secretary-Treasurer, until 1990, when he was elected President-Elect. In 1991-92 he served with distinction as President of the Association. He has been active in various aspects of his community and is a veteran of World War II, having landed with the 4th Marine Division at Iwo Jima.

Dr Scheen's list of accomplishments and contributions cannot be fully enumerated in this article. He is a recipient of the KMA Distinguished Service Award, the highest award the Association bestows; he was among the group of KMA leadership who formed the Kentucky Medical Insurance Company in 1978, and has served on that Board since its inception; and when the issue of the Kentucky Physicians Care program was first considered, he urged the KMA Board to adopt the Ad Hoc Committee's recommendation — not for the benefit of the politics of the program — but because it was the right thing to do.

In his presentation, Dr Monnig stated, "There have been few physicians who have given more of themselves and their time to the profession than Randy Scheen. When you consider the number of Board meetings, executive Committee meetings, Quick Action Committee meetings, Judicial Council, legislative meetings and other Committee meetings, including the Budget Committee and Ad Hoc Committee meetings, it is phenomenal the amount of time it took from his practice. Someone once estimated that he signed over 75,000 checks for KMA. That is just a small example of the time he made available for administrative purposes at KMA."

Dr Monnig also included Mrs Scheen, in photo above, in his tribute. "Randy and his lovely wife, Betty, have been a fixture of this Association for many years and have been a source of pride for all of us. They truly represent the best in medicine." KMA

PEOPLE

Two KMA members were recently included in a group recognized as winners of the University of Louisville's Young Investigator Awards. **Michael J. Edwards, MD,** works within the surgical oncology division and as an associate of U of L's center of excellence in applied microcirculatory research. He has been in the news lately for his work with other faculty on reducing the life-threatening side effects of the cancer-treating agent interleukin-2 without hindering its effectiveness. Dr Edwards also has won the American Cancer Society's junior faculty fellowship and its career development award in recent years.

Gary S. Marshall, MD, a pediatrician, is noted for his research on a type of vaccine for cytomegalovirus, as well as for his expertise on chronic fatigue syndrome for children. Dr Marshall was recognized by the U of L pediatric faculty and house staff as the outstanding clinical professor in 1992. He serves as an editorial reviewer for several journals related to pediatrics and disease, and has authored numerous publications.

Clovis A. Crabtree, MD, Louisville, was recently selected as Southern Medical Association's State Councilor from Kentucky. Dr Crabtree joins 16 other state representatives along with SMA officers in comprising the governing body of the Association known as the Council. A specialist in psychiatry, Dr Crabtree is affiliated with Ten Broeck Hospital in Louisville.

David H. Neustadt, MD, was named a Master of the American College of Rheumatology during opening ceremonies of the scientific meeting in Atlanta recently.

Jane R. Bramham, MD, of Bowling Green, recently received a 3-year appointment as Cancer Liaison Physician for the Hospital Cancer Program at Medical Center at Bowling Green. The Cancer Liaison Program is an integral part of the Commission on Cancer of the American College of Surgeons.

Radiologist **Ina D. Tonkin, MD,** has been appointed as Distinguished Scientist at the Armed Forces Institutes of Pathology in the Department of Radiologic Pathology.

UPDATES

U of L Physicians Named to "Best Doctors in America" List

The University of Louisville reports that several of their physicians were featured in the latest edition of "The Best Doctors in America," a listing of the nationally recognized physicians in the United States. The U of L list included KMA members **Jeffrey P. Callen, MD,** dermatology; **Thomas A. Golper, MD,** nephrology; **Joseph E. Kutz, MD,** hand surgery; **Robert D. Lindberg, MD,** radiation oncology; **Serge A. Martinez, MD,** otolaryngology; **David H. Neustadt, MD,** rheumatology; **Hiram C. Polk, MD,** general surgery; and **Joseph S. Sanfilippo, MD,** obstetrics and gynecology. Doctors were selected for the book based on surveys of their colleagues nationwide.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Adair

Richard Lenaghan, MD — S
105 Westlake Dr, Columbia 42728
1956, U of Melbourne

Boyd

Gregory D. Cox, DO — C
4458 Azalea Dr, Ashland 41102
1985, Kirksville Col of Osteopathy

Roy M. Stefanik, DO — P
619 12th St, Ashland 41101
1988, Col of Osteopathy, Des Moines

James S. Wagenaar, DO — IM
6636 Hickory Hills, Ashland 41102
1987, Michigan State Col of Osteopathy

Boyle

Arthur K. Rivard, MD — OPH
208 Bluffwood Dr, Danville 40422
1986, U of Kentucky

Clay

Raymundo P. Punzalan, MD — END
317 Town Branch Rd, Manchester 40962
1981, U of the East, Philippines

Raghuraman Srinivasan, MD — IM
PO Box 369, Manchester 40962
1988, Seth Medical Col, India

Daviess

Robert M. Kirk, MD — GE
PO Box 1322, Owensboro 42302
1980, U of Louisville

Fayette

Luis E. Bolano, MD — ORS
KY Clinic K401 UKMC Lexington 40536
1986, Baylor

Richard S. Jerauld, MD — ID
1221 S Broadway, Lexington 40504
1973, Case Western Reserve

Daniel S. Rowe, Jr, MD — AN
2616 Clubside Dr, Lexington 40513
1979, Jefferson Medical Col

Harlan

Dorel Abramovici, MD — OBG
94 Ballpark Rd, Harlan 40831
1986, Tel-Aviv U

Robin S. DaCosta, MD — IM
94 Ballpark Rd, Harlan 40831
1989, New York U
Lincoln M. DeSouza, MD — U
94 Ballpark Rd, Harlan 40831
1954, Federal U of Minas Gerais

Jefferson

Clara P. Comer, MD — EM
PO Box 6653, Louisville 40206
1975, U of Louisville
Harvey L. Edmonds, PhD
3712 Plymouth Rd, Louisville 40207
1974, U of California, Davis
Julius T. Gavin, Jr, MD — ORS
1402 Browns Ln, Louisville 40207
1977, U of Kentucky
Bhupendra K. Gupta, MD — P
6904 Fallen Leaf Cir, Louisville 40241
1974, Kasturba Medical Col
John F. Sampson, MD — AN
233 E Gray #612, Louisville 40202
1970, Medical Col of Georgia
Timothy E. Schmitt, MD — OPH
519 State St, New Albany, IN 47150
1976, Indiana U
George P. Stacy, Jr, MD — C
4003 Kresge Way #221, Louisville 40207
1986, Duke U
Alan D. Wilkinson, DMD — DENT
4010 Dupont Cir #569, Louisville 40207

Knox

William S. Black, MD — FP
PO Box 399, Barbourville 40906
1990, U of Kentucky

Leslie

Anita F. Cornett, MD — IM
PO Box 680, Hyden 41749
1987, U of Kentucky

Letcher

Imran M. Bajwa, MD — IM
PO Box 1030, Whitesburg 41858
1986, Allambra Iqbal Medical Col
Ricky E. Collins, MD — FP
105 S Webb Ave, Whitesburg 41858
1985, W American U of the Caribbean

McCracken

Kevin E. Stigall, MD — S
4 Hickory Hill, Paducah 42001
1984, U of Tennessee

Nicholas

Geoffrey A. Peters, MD — GP
114 Oriole St, Carlisle 40311
1984, U of Toronto

Northern Kentucky

C. Duane Bellamy, MD — AN
13 Bittersweet Dr, Alexandria 41001
1985, U of Cincinnati
Stephen Schuler, DMD — DENT
20 Medical Village Dr, Edgewood 41017
Raymond J. Sullivan, MD — AN
20 Medical Village Dr, Edgewood 41017
1985, State U of New York, Syracuse

In-Training

Fayette

Catalin D. Jurnalov, MD — OBG
E. Wayne Mosley, MD — ORS
Steve L. Roberts, MD — OBG
Damain A. Smith, MD — OBG

Jefferson

Craig A. Dopf, MD — ORS

DEATHS

Samuel L. French, MD
Paducah
1912-1993

Samuel L. French, MD, a retired orthopaedic surgeon, died January 1, 1993. Dr French graduated from the University of Maryland School of Medicine in 1943 and was a life member of KMA.

Carroll L. Witten, MD
Louisville
1923-1993

Carroll L. Witten, MD, a family physician, died January 5, 1993. He was a 1951 graduate of the University of Louisville School of Medicine and became a member of KMA in 1951.

Gradie R. Rowntree, MD
Louisville
1903-1993

Gradie R. Rowntree, MD, a retired occupational medicine physician, died January 17, 1993. He taught at U of L from 1939 to 1981 and served as president of the U of L Health Sciences Library. The Humana Hospital-University of Louisville Library is named for him. Dr Rowntree graduated from the University of Arkansas School of Medicine in 1932 and was a life member of KMA.

Harry J. Cowherd, MD
Frankfort
1929-1993

Harry J. Cowherd, MD, a family physician, died January 18, 1993. Dr Cowherd was secretary of the Cabinet for Human Resources during the Wilkinson administration, and was former head of the Cabinet's disability-determination unit. He graduated from the University of Louisville School of Medicine in 1955 and was an active member of KMA.

Governor Jones Releases Plan

In mid-February, KMA obtained a copy of Governor Brereton Jones' revised health care reform plan released to legislative leadership. The plan was still in draft form, and a final plan was expected soon thereafter. Governor Jones had indicated that a special legislative session was targeted for mid-March and that prior to the special session, a campaign would be scheduled to get public support for the plan. The following is a summary of the Governor's plan with areas of special interest to physicians in Kentucky and the KMA position highlighted in various sections.

The Health Care Authority
Seen by many as the most onerous provision of the Governor's proposal, the Authority would be composed of five individuals, chaired by the CHR Secretary, who would have broad powers to control and micro-manage the health care system, including establishing and monitoring global budgeting; immediate rate setting and/or reducing professional fees as a cost control mechanism; assessing/planning/authorizing reimbursement and establishing new technology; developing/supervising regional health care delivery systems; setting medical school curriculum and residencies; and assuming powers of the Kentucky Board of Medical Licensure. *The Kentucky Medical Association opposes placing such extensive controls in the hands of a few individuals.*

Insurance Reform
The plan outlines a system of standardizing insurance billing procedures; eliminating preexisting condition clauses; eliminating waiting periods; rewarding providers in underserved areas; and using community rating. *The KMA is in support of these concepts.*

Universal Access
This section calls for requiring employers to provide insurance for employees and placing a 10% payroll tax for businesses that fail to provide insurance to employees; subsidizing vulnerable small businesses; insuring children under Medicaid to 200% of the federal poverty level; increasing Medicaid eligibility for adults; and mandating individuals to purchase health insurance, while placing a fine of $200 on each individual who fails to get insurance after January 1, 1994. The uncertainty behind this section relies on the granting of federal ERISA waivers.

Health Care Delivery Reform
This section highlights emphasizing primary preventive care through medical school curriculum; increasing financial incentives for primary care residencies; increasing compensation of primary care physicians; placing a cap on funding for nonprimary care residencies; and granting prescriptive authority and reimbursement privileges to physician assistants and advanced registered nurse practitioners. *While KMA is supportive of increased primary care accessibility, we are concerned with interference in medical school curriculum.*

Consumer Education/Protection
This portion of the plan involves requiring school health be taught in grades K-12; promoting healthy lifestyles; and requiring seat belt usage statewide. *KMA has consistently been supportive of these principles.*

Proposed Funding-Provider Tax
The funding mechanism proposed involves utilizing $5 million from general revenue for administrative costs of the Health Care Authority; $38.7 million from a 2% tax on physicians' total patient revenues (which replaces the existing Medicaid tax); $121.7 million from a 4% tax on hospital patient revenues; $27.5 million from a 5.5% tax for nursing facilities; $1 million from a 2% tax on patient revenues of intermediate care facilities for the mentally retarded; $6.3 million from a .25 cent tax per prescription; $2 million from a 2% tax on home health agencies; and $6.3 million from a 5% tax on HMOs.

The facts surrounding this issue are as follows: Since 1991, physicians treating Medicaid patients have been taxed at a rate of 15% of their Medicaid reimbursement. The federal government, in turn, reimburses the state $3 for every $1 raised from the Medicaid tax. The state retains one-half of the total proceeds and returns the other to physicians in the form of increased reimbursement. In 1992, Congress prohibited this arrangement, requiring that all providers of a given class be taxed at the same rate and prohibiting built-in incentives such as Kentucky's two-for-one guaranteed rate of return to physicians.

As a result of 1992 federal Congressional action, this provision sunsets on July 1, 1993. Without this current tax on hospitals, physicians and other providers, the loss of revenue to the state Medicaid budget has been esitmated to be approximately $400 million and, according to the Kentucky Cabinet for Human Resources, physicians would experience a 50 to 75% reduction in Medicaid fees and approximately 100,000 Medicaid participants would be removed from the roles. The

potential revenue loss concerns the Governor's administration and the General Assembly which must consider ways to maintain health care for Medicaid recipients if provider reimbursement is reduced, plus the loss of coverage for 100,000 people. A broad-based tax, or any other tax, "is not an option" according to the Governor and state legislators. *The 1992 KMA House of Delegates voted to oppose a tax on health care providers believing that funding for health care should be a societal responsibility.*

Medicaid Reform

Gives the Health Care Authority the duty of negotiating contracts for state employee health benefits and for other groups in the state megapool, including the Medicaid population.

The authority would also require that if a physician is seeing one patient from the megapool, then any patient from the megapool must be seen. The Medicaid Program would include coverage of optional categorical groups which do not require federal waivers, such as pharmacy services for the elderly and disabled under 100% of the federal poverty level, and coverage of all children and families with incomes below 200% of poverty. Waivers have been requested to cover all Kentuckians below 100% of poverty. Additional waivers will be requested to provide other assistance for low income unemployed persons and Medicare beneficiaries. Members of the pool shall include public employees of the universities and colleges, cities and counties, Medicaid recipients, uninsured unemployed persons, prisoners, wards of the state, and other state employees. Other individuals and groups may participate in the pool as an alternative to purchasing private insurance. The major focus of the proposal "privatizes" Medicaid by bidding out groups of the pool to private insurers for implementation through various managed care plans. The current KenPAC program, which utilizes a primary care physician as a gatekeeper, will continue only in those regions where private managed care or prepaid plans are not available or are not competitive.

Control of Medical Schools and Residencies

We believe many of the proposals relating to medical schools to be extreme and have the potential to lower the high standards and quality of medical schools in Kentucky. Based on limited information, it would appear Kentucky's brightest medical students may seek their medical education elsewhere and highly qualified out-of-state students would not choose Kentucky medical schools.

We remind you that this proposal is the Governor's plan and not the work of the Legislature. We urge you to contact legislators to discuss the Governor's proposal. Most of them still have an open mind on this issue and would like to hear from their constituents. Officers and staff of the KMA are available to answer any questions or make presentations on health care reform. KMA



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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility. In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitounnary				
Unnary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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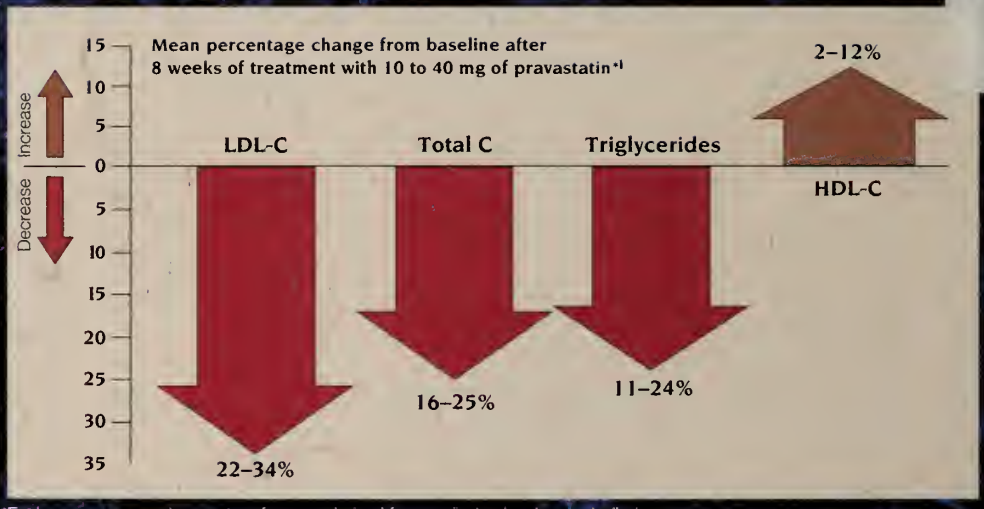
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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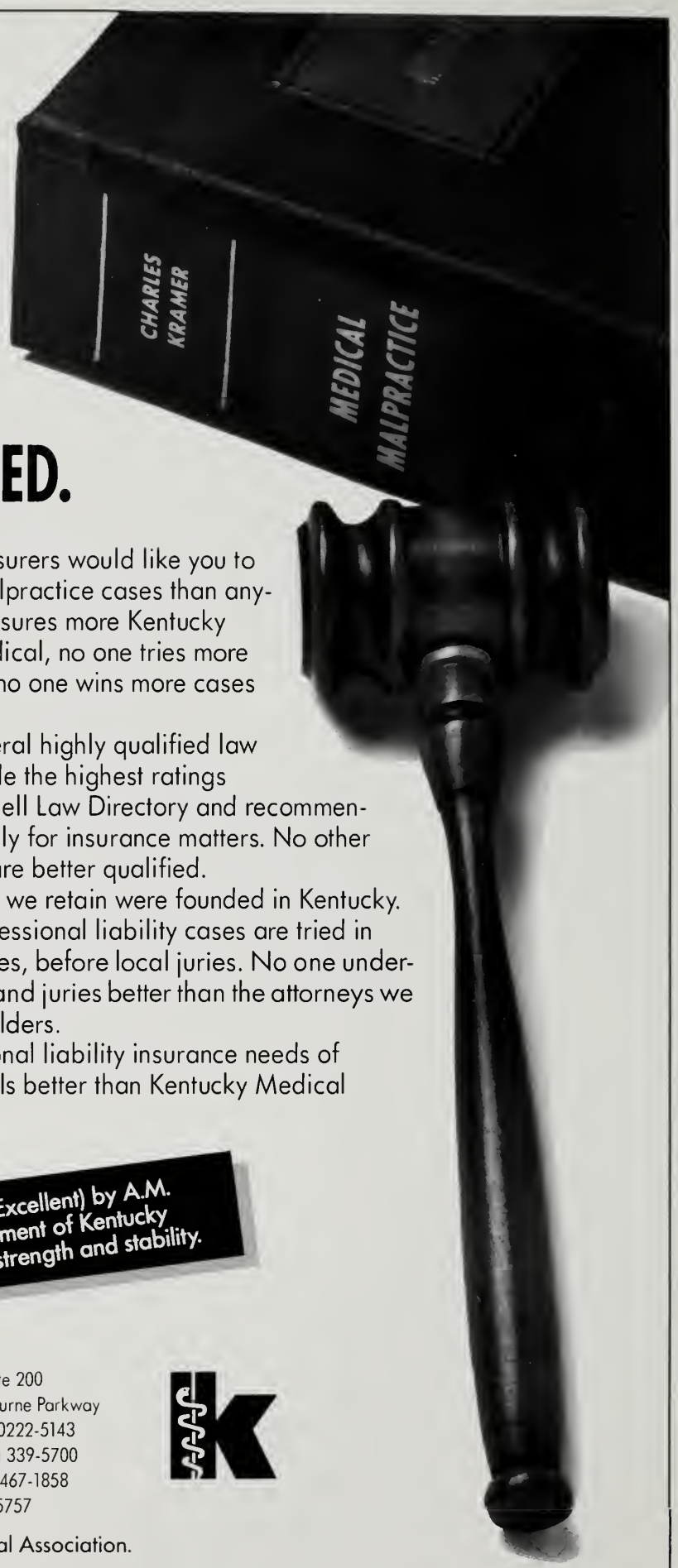
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Coal Workers' Pneumoconiosis and Compensation in Kentucky



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COVER: A report of a typical case of Black Lung disease and the status of workers' compensation for this disease in Kentucky begins on page 136. Artwork and design by Lee Wade of Louisville.

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William B. Monnig, MD

Masters of Change?

"We cannot prevent change nor should we. We can be "masters of change," or we can be slaves of change . . . we need to seize the opportunity . . . to make the necessary sacrifices of financial security and of individual freedom to take control of our destiny."

Change in the health care system is inevitable. Not only is it inevitable but imminent. Physicians, through training, are accustomed to being in control of themselves and their immediate external environment. Physicians are taught to observe, assess, evaluate, prioritize, consider all potential alternatives, and then initiate action. We constantly re-evaluate the changing situation, and alter our actions to achieve our goal. We have an attitude that we are able to control the outcome better than anyone else. We can accept the inevitable if the disease process or deterioration of life processes cannot be controlled. But through training and experience, we develop a self confidence that, if the process can be controlled, we are best equipped to accomplish the task. Our self esteem is bolstered through our daily encounters with patients and their diseases.

Physicians routinely need to create structure and process to produce the patient outcomes that we strive for. We function well only when we maintain control of ourselves and our environment. We do not take offense at constructive criticism, but we bristle when others interfere with, or disrupt, our diagnostic or therapeutic treatment plans without consulting us. I realize that this description of doctors' thought processes is an oversimplification, but it does help us understand why most physicians are so frustrated with dealing with health care reform. I believe that changes in health care delivery are inevitable. Physicians cannot maintain the status quo. We cannot control the environment in which the debate is being formulated. We have not established "deemed status" as the authorities on health care delivery that would allow us to dictate corrective action to improve the prognosis for our "flawed" (diseased) health care system. We have been unable to effectively communicate the problems or solutions to those who would depend on us.

We have an opportunity. We cannot prevent change nor should

we. We can be "masters of change," or we can be slaves of change. I believe we need to seize the opportunity. We need to make the necessary sacrifices of financial security and of individual freedom to take control of our destiny. I am convinced that patient care will suffer dramatically if physicians do not adjust to the changing environment. If we wish to continue to maintain control over individual patient's care, we must be willing to organize ourselves in such a way that we can meet the needs of group purchasers of health care. We must begin to explore alternative methods of joining together to maintain political control over patient care. If the government, or business, or other payors are successful in convincing society that artificial limits will be placed on health care expenditures, then we need to be in position to assure that those dollars are spent in the most appropriate way.

If rate setting or global budgets become a reality, insurers may become a liability, and yet they will have a strong desire to control segments of the global budget. If the health care resources are artifically limited and in-patient care continues to diminish, hospitals' traditional role will be de-emphasized, but they will have an inherent desire to expand their control over out-patient services. In this era of change, physicians have the opportunity to maintain control over the outpatient care that has been traditionally ours. The fact that outpatient care is becoming an ever increasing portion of the health care pie should be to our advantage.

We must learn to work in partnerships — amongst ourselves, with hospitals, and with intermediaries. We will need to realign our thought processes to encompass cooperation in redefining equitable reimbursement for professional services; in maintaining health rather than treating disease; in defining those cost effective ways of diagnosing and treating disease; in promoting and nurturing the professional nature of physician practice.

We must embrace the essence of large groups of physicians working together if we wish to maintain control of change in health care delivery. There are other alternatives: We can give up our freedom to manage change; we can overtly cede the process to hospitals by becoming their employees; or we can covertly cede the process to insurance entities through employment contracts or individual participation contracts.

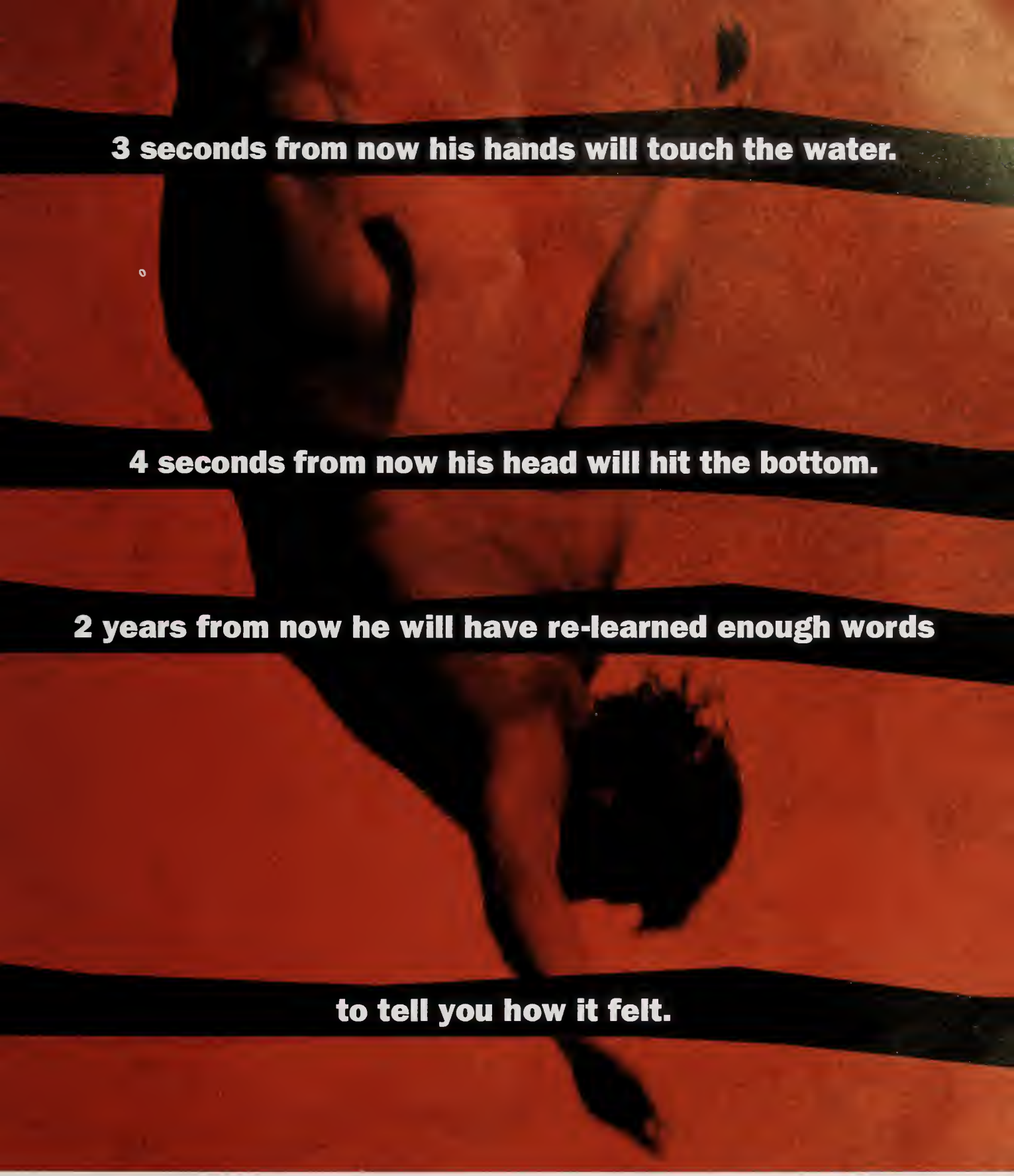
No physician can insulate himself or herself from the change. Rural physicians, who are in undersupply, run the risk of being controlled by publicly funded and directed delivery entities. Primary care physicians, who are as busy as they can be under the present system, run the risk of being forced into unwanted alliances with limited licensed practitioners. Hospital based physicians run the risk of enforced employment by the hospital. Surgeons and medical proceduralists run the risk for contractual exclusion from access to patients, of economic credentialing by hospitals, and of unreasonable financial constraints by consumer representatives.

There is plenty of incentive for physicians to re-examine their organizational structures, to vigorously explore alternative structures that will meet the needs of external change.

There is an opportunity to maintain control of medicine's destiny, to maintain control of our professional destiny. Will we take advantage of the opportunity? Each one of us must be willing to assume some risk. The KMA is ready to assist our members, but a personal initiative is essential.

Will we be masters of change or slaves to change?

William B. Monnig, MD
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Coal Workers' Pneumoconiosis and Compensation in Kentucky

B. T. Westerfield, MD, FCCP

Coal Workers' Pneumoconiosis has been a compensable disease since the 1960s. In 1987 the Kentucky Workers' Compensation Law was changed to provide reduced benefits for coal miners with radiographic evidence of Black Lung Disease, but little or no respiratory impairment. This paper reports a typical case of Black Lung today and discusses the status of workers' compensation for this disease in Kentucky.

Coal Workers' Pneumoconiosis (Black Lung) continues to exist in Kentucky today. Despite 30 years of government regulation and intervention to try to halt this disease, applications for Workers' Compensation benefits due to Black Lung have continued to increase (Table 1).

Black Lung has long been more important as a legal disease than a medical one. With the federal and state Black Lung Acts in the 1960s, Coal Workers' Pneumoconiosis became a compensable disease and benefits were extended to active and retired coal mine workers and beneficiaries. Attorneys and physicians alike prospered from a backlog of cases. In 1987, the Commonwealth of Kentucky changed the Workers' Compensation law to offer retraining incentive benefits (RIB) to workers with radiographic evidence of Black Lung, but little or no respiratory impairment.[1] The goal was to identify injured workers and compensate for the injury but discourage lifetime payments when no actual disability existed. What can the coal miner today and those who care for him expect from an application for Black Lung Compensation?

Case Report

A 42-year-old white male from Eastern Kentucky was referred to Commonwealth Respiratory Consultants by his attorney for evaluation of possible Coal Workers' Pneumoconiosis. The miner reported few respiratory symptoms including mild shortness of breath with extra exertion and occasional dry cough. His past respiratory history was notable only for a questionable episode of pneumonia as a child. He had no history of asthma, tuberculosis, and had *never* smoked cigarettes. He did not feel limited by his shortness of breath but reported he was more "short-winded" than he used to be when he exerted himself. Other medical history was unremarkable. The patient had worked general labor on construction for 4 years, 17 years in underground coal mines, and the past 3 years in surface mining. He had had various jobs underground, including operating a roof bolter, continuous miner, and shuttle car. He had been a truck driver during his entire service in strip mining, and that is his present job.

Physical examination revealed a healthy male with no abnormal chest findings. Chest radiograph showed scattered, rounded densities in the mid and upper lung fields categorized as "p/q" with profusion of 1/1, based on the 1980 ILO International Classification of Radiographs. (Chest x-rays interpreted for Black Lung are compared to Standard Radiographs from the International Labor Organization for the presence of small opacities and the profusion density of the opacities.) Spirometry was normal with FEV_1, 3.35

Dr Westerfield is Medical Director, Commonwealth Respiratory Consultants, 3174 Custer Drive, Lexington, KY 40517.

Table 1. Black Lung Claims

Year	No. Filed	Full Award	RIB
1987	819	599	—
1988	421	500	—
1989	740	767	9
1990	725	831	208
1991	915	561	185

Data from Labor Cabinet Division of Special Fund
RIB — Retraining Incentive Benefits

Table 2. Black Lung Benefits — 1987 Law

Tier	Radiographic Class	PFT	Payments
I	1/0, 1/1, 1/2	FEV_1, FVC >80%	208 Weeks
II	1/0, 1/1, 1/2	FEV_1, FVC >55% <80%	425 Weeks
III	1/0, 1/1, 1/2 or 2/1 — 3/3	FEV_1, FVC <55%	Lifetime

(86% predicted), FVC 4.38 (90% predicted), and FEV_1/FVC 76%. Arterial blood gases were pH 7.42, pO_2, 86, pCO_2 38, O_2 saturation 97%. The coal miner was felt to have Coal Workers' Pneumoconiosis, Category 1, with no respiratory impairment.

Discussion

Coal Workers' Pneumoconiosis is a disease resulting from inhalation of carbon particles, occurring most commonly as coal dust in the coal mining industry, and the lung's reaction to the dust so deposited.[2] "Black Lung" is a legislatively defined term encompassing the medical definition of Coal Workers' Pneumoconiosis but is defined by the Federal Coal Mine Health and Safety Act of 1969 as a "chronic dust disease of the lung arising out of employment in coal mining."[3] The estimates of the number of miners afflicted with Black Lung vary considerably. An early 1970s study in Appalachia showed a 10% incidence of Black Lung,[4] and a 1977 study of surface coal miners found the incidence of radiographic CWP as 4%.[5] Depending on the degree of coal dust exposure and the years in the coal mines, the incidence may be as high as 33%.[3] Over 7,000 Black Lung claims have been awarded in Kentucky prior to 1987[6] and 3,660 claims awarded since the law was changed (Table 1).

Pathologically, Coal Workers' Pneumoconiosis is characterized by the coal macule — deposits of anthracotic pigment unassociated with fibrosis — and the presence of fibrosis itself.[2] Coal macules show up as rounded opacities on chest roentgenograms and usually cause little pulmonary impairment. The presence of these densities (smaller than 1cm) defines "simple" pneumoconiosis. Radiographic categories have been devised by the International Labor Organization to grade the profusion of these densities from 0 to 3 on the chest x-ray. These major categories are then subdivided (eg, category 1 is 1/0, 1/1, 1/2) to form a 12-point scale of profusion recognizing the gradation of change from negative to the most advanced category.[7]

Larger opacities (greater than 1 cm in diameter) represent "complicated" pneumoconiosis or progressive massive fibrosis and occur principally in the upper lung fields, sometimes encompassing an entire lobe. Almost all miners being evaluated for CWP report shortness of breath. Cough and sputum production may be present. Signs and symptoms correlate more with presence of progressive massive fibrosis than simple pneumoconiosis. Symptoms in simple pneumoconiosis are more related to a positive smoking history than radiographic abnormalities. Pulmonary function studies are frequently normal in simple pneumoconiosis but can be very deranged if PMF is present. In Kentucky miners, silicosis may also be present due to rock encountered in thin coal seams underground and rock drilling in surface mining. With limited silica exposure, the chest radiograph will show the small opacities associated with coal dust rather than classic changes associated with silicosis. However, if the silica exposure was substantial, the x-ray may show nodular densities, calcifications, fibrosis, and lymph node enlargement.

There are now three tiers of compensation for Black Lung (Table 2). Workers with radiographic category 1 and normal pulmonary function (FEV_1, FVC greater than 80% predicted) can receive 208 weeks (4 years) of benefits. Workers with radiographic category 1 who have mild to moderate respiratory impairment (FEV_1, FVC greater than 55% predicted but less than 80% predicted) are given an AMA disability rating of 75% and receive increased benefits for 425 weeks (8-¼ years). Workers with radiographic category 1 and less than 55% predicted FEV_1, FVC, or with radiographic category 2 and higher are considered totally disabled and are eligible for lifetime compensation benefits.

As in the past, Black Lung payments are shared by the most recent coal employer and the Kentucky Department of Workers' Compensation Division of Special Fund. Payment of retraining incentive benefits is the sole responsibility of the employer in whose employment the worker was last exposed to coal dust.[1]

This coal miner falls into Tier I for a Black Lung claim and is eligible for 4 years of retraining incentive benefits. He may receive these semi-

monthly if he continues to work in coal mining, or in a lump sum if he has left such employment. There is no provision for any of the funds to go toward actual job retraining. Furthermore, the payment may be less if the worker agrees to an early lump sum settlement in lieu of a contested case by the employer's insurance carrier. His benefits will be paid by his most recent employer, which was in surface mining, even though most of his exposure was in previous underground coal mining.

If this miner continues in the coal mining industry — and the law prevents discrimination against him because of a present Black Lung claim — he may reapply for further benefits if there is progression of his lung disease into a greater radiographic category or evidence of deterioration of lung function.

In summary, Coal Workers' Pneumoconiosis continues to be present in Kentucky and there is an increase in applications for Black Lung benefits. Whether from noncompliance with the law or from insufficient standards, coal dust continues to be inhaled in the coal mining environment. The weakened coal economy and unemployment have also contributed to new applicants seeking compensation benefits. This paper has outlined the present status of Coal Workers' Pneumoconiosis in Kentucky. All coal miners who have a significant coal and dust exposure need to be fairly evaluated and identified. If Black Lung disease is present, then the miner needs to have his future dust exposure limited and be justly compensated for the injury.

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Lemierre's Syndrome Caused by *Fusobacterium necrophorum*: A Case Report

Makoto Aoki, MD; Robert C. Noble, MD; Edward J. Scott, MD; Gregory V. Osetinsky, MD

Fusobacterium necrophorum is an anaerobic gram-negative rod which causes a rare infection of oropharynx often resulting in serious complications including jugular vein thrombophlebitis and metastatic infections. Early recognition and prompt treatment with appropriate antibiotics is essential. The following is a report of a patient with pharyngitis and *Fusobacterium necrophorum* bacteremia without serious sequelae.

Case Report

An 18-year-old black female college student was admitted to the St. Claire Medical Center in Morehead, Kentucky, with a 3-day history of a severe sore throat, chills, and fever to 105°F. The sore throat was accompanied by right ear pain, and for 3 days she had had difficulty swallowing. The patient denied preceding headache, conjunctivitis, cough, rhinorrhea, nausea, vomiting, or diarrhea. Two days before the admission, the patient visited a clinic and had a negative throat culture for streptococcal infection. She was thought to have a viral infection, and received no antibiotics. She did take "a dose of penicillin from a friend" on the day of admission to the hospital. The patient was not on any regular medication and had no prior illnesses. She had regular dental care and did not have cavities or periodontal disease.

Physical examination on admission revealed an obese young woman, weighing 110 kilograms, complaining of a sore throat. Her vital signs were; blood pressure 112/72 mm Hg (supine), 62/48 mm Hg (standing); pulse, 154 beats per minute; temperature, 103.3°F; and respirations 28 per minute. Her physical examination was within normal limits except for bilaterally enlarged tonsils which were covered with a white exudate. There was marked tenderness in the right lateral pharyngeal area and tenderness also in the right anterior and posterior cervical region as well as the right submandibular region. The uvula was not deviated. The neck was supple and no jugular venous distension was noted. The laboratory examination showed the following significant values: hematocrit, 39%; leukocyte count 19,200/mm^3, 86 segmented neutrophils, 10 band forms, 2 lymphocytes, and 2 monocytes. The urinalysis was within normal limits. A Monospot test (Mono-test, Wampole Co, Cranbury, NJ) and Strept Screen (Directigen, Dickenson Co, Cockeysville, MD) were negative. The electrolytes, blood urea nitrogen, and serum creatinine were within normal limits. The chest roentgenogram was unremarkable.

The patient was treated with intravenous fluid for orthostatic hypotension and begun on 2 million units of aqueous penicillin G intravenously every 4 hours. On the second hospital day, oral metronidazole, 500 mg, was added every 6 hours even though she was improving. A computerized tomography scan of the head and neck showed no abscess. On the third hospital day, a blood culture obtained at the time of admission grew a gram-positive coccus and a gram-negative rod. Cefotaxime, 2 grams intravenously every 6 hours, replaced the penicillin G, and gentamicin, 150 mg intravenously every 8 hours, was also started. On the fifth hospital day, the organisms in the blood culture were identified as *Staphylococcus epidermidis* and *Fusobacterium necrophorum*. Cefotaxime and gentamicin were discontinued, and three million units of aqueous penicillin G every 4 hours was again started intravenously. The metronidazole dose was increased to 750 mg and given intravenously every 6 hours. The patient was transferred to the University of Kentucky Medical Center for further observation. On admission, patient was afebrile and had moderate induration and tenderness over the right submandibular and middle anterior neck region. The tonsils were still swollen and were covered

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with a white exudate. Magnetic resonance imaging of the head and neck and carotid angiography with internal jugular vein imaging showed no evidence of vascular involvement. The patient remained afebrile throughout the hospital course and completed a total 10 days of intravenous antibiotics. She was discharged on metronidazole 500 mg orally every 6 hours for an additional 7 days. The patient remained well at a follow-up of 1 month.

Discussion

Fusobacterium necrophorum, an anaerobic gram-negative rod, is a rare cause of sepsis in patients with pharyngotonsillar infection. As in our case, *F necrophorum* sepsis typically occurs in young adults in good health who have acute oropharyngeal infection. This is often complicated by secondary septic thrombophlebitis of the internal jugular vein and multiple metatastic abscesses of the lung and other sites. This syndrome is named for Lemierre who described it as "postanginal septicemia" in 1936.[1] Recent reviews indicate that only 38 cases of the syndrome have been reported since 1974.[2] The rarity of *F necrophorum* bacteremia through the 1970s may be due in part to the widespread use of antibiotics in patients with pharyngitis. Since the throat culture was negative and she was thought to have a viral infection, our patient did not receive antibiotics for 2 days. Severe sore throat, a sore neck, and fever were her only symptoms. The lack of antibiotic therapy may have facilitated the isolation of *F necrophorum.*

The choice of antibiotics in these patients can be difficult. Seidenfeld et al reported four cases of *F necrophorum* infection initially treated with a penicillinase-resistant penicillin because of embolic pulmonary lesions thought to be indicative of a *Staphylococcus aureus* infection.[4] The isolation of a rapidly growing organism such as *Staphylococcus epidermidis* in our case misguided the choice of antibiotics, as well.

Our patient had no signs or symptoms of metastatic foci of infection as demonstrated by the chest roentgenogram or by the examination of the head and neck with computerized tomography, magnetic resonance imaging, and carotid angiography. She was placed on high dose penicillin therapy 3 days after the onset of her symptoms, and this may have helped to prevent a variety of complications. Penicillin G is usually effective for most of the oropharyngeal flora including *F necrophorum.*[5] Metronidazole is also an effective therapy.[6] The optimal regimen is not known, but penicillin G, ampicillin, chloramphenicol, and cefoxitin are reported to be effective as well.[2,3,4] Finally, the duration of the antimicrobial treatment in our uncomplicated case was only 18 days, but cases with metastatic lesions need a prolonged course of antibiotics and possibly surgical drainage to achieve a complete cure.

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Re-Expansion Pulmonary Edema: A Preventable Complication

Susan E. Janocik, MD; Thomas M. Roy, MD; Timothy R. Killeen, MD

Ipsilateral pulmonary edema may occur in a lung that has been rapidly reinflated after a variable period of collapse resulting from pleural effusion or pneumothorax. The syndrome of re-expansion pulmonary edema is associated with variable degrees of hypotension and hypoxemia with some patients experiencing cardiac arrest and death. Although the number of cases reported in the medical literature is small, the actual incidence of this potentially avoidable complication is unknown. It may go unrecognized by the clinician as a primary contributor to an adverse outcome.

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The first clinical description of a patient experiencing re-expansion pulmonary edema was published 90 years ago.[1] This potentially fatal complication of therapeutic thoracentesis or tube thoracoscopy for pneumothorax continues to be chronicled in the medical literature primarily as single case reports. Many physicians, therefore, remain unaware of the possibility of unilateral edematous lung injury following these procedures. This is unfortunate since the problem of high permeability pulmonary edema after lung re-expansion is easily avoidable if the clinical predictors are recognized.

This review will emphasize the clinical setting in which re-expansion pulmonary edema is most likely to occur and examine the various physiologic explanations, which have been proposed in the last decade, for this phenomenon.

Case Report

The patient was a 50-year-old male admitted after a 4-day history of progressive shortness of breath on exertion and, finally, at rest. He had experienced a transient mild pleuritic discomfort on the left side during a severe coughing episode 5 days earlier, when exposed to a mixture of cleaning solvents at home. The coughing persisted for only 1 day and was nonproductive. He denied fever, chills, or exposure to infectious disease. He had gradually developed respiratory discomfort when lying supine or on his left side.

His past history was unremarkable except for mild hypertension. He smoked one pack of cigarettes each day for the last 30 years. He works as an assembly line foreman for a manufacturing plant.

Physical findings on admission included a slightly deviated trachea to the right, hyperresonance to percussion of the left hemithorax with diminished breath sounds, and distant normal heart sounds. Pulse was 82 BPM and blood pressure was 140/90 mm Hg. He was not cyanotic. He was tachypneic with 22 respirations per minute, but was not uncomfortable in the seated position.

Supplemental oxygen was provided by nasal cannula because the patient was dyspneic. Oxyhemoglobin saturation was 98% by pulse oximeter. Chest radiograph showed nearly complete left pneumothorax. A 32 Fr chest tube was inserted and a second radiograph was obtained to confirm the tube position. This film failed to show reinflation (Fig 1). The chest tube was attached to continuous negative pressure to expand the parenchyma. Another chest radiograph was ordered.

Approximately 45 minutes after the application of negative pressure to the chest tube, the patient became confused, cyanotic, and in respiratory distress. Oxyhemoglobin saturation fell to 86% by pulse oximeter and failed to improve with a 50% face mask. Pulse increased to 120 BPM and blood pressure increased to 180/110 mm Hg.

The patient was electively intubated without difficulty and oxygenated with 60% oxygen and positive end expiratory pressure of 10 cm H20. The pre-intubation radiograph confirmed the presence of unilateral pulmonary edema. The



Fig 1 — PA chest radiograph shows incomplete re-expansion of a left sided pneumothorax despite satisfactory chest tube placement.



Fig 2 — Re-expansion of the left lung with 20 cm H_20 continuous negative pressure to chest tube. Re-expansion pulmonary edema is evident in left lung.

chest tube was placed to water seal. The patient improved and was able to oxygenate without ventilator support on the fourth day. He was discharged after successful pleurodesis was accomplished on the left side by tetracycline instillation.

Discussion

Re-expansion pulmonary edema (RPE) is an acute, unilateral lung injury that may follow rapid reinflation of a collapsed lung. When collapsed areas of alveoli are suddenly re-expanded by large volume thoracentesis or tube thoracoscopy with application of continuous negative pressure by suction, the previously atelectatic parenchyma must undergo rapid reperfusion by the pulmonary artery and resumption of alveolar ventilation with new exposure to oxygen.[2] These events may be followed by a form of high permeability pulmonary edema that is usually confined to the hemithorax that contains the re-expanded lung.

The intra-alveolar flooding from increased capillary permeability creates a situation of hypoxemia since the re-expanded lung is now fully perfused but without effective gas exchange. The impaired oxygenation acts as a true shunt without significant improvement despite the provision of supplemental oxygen.[3] The resultant fall in PaO_2 may be severe enough to cause general tissue hypoxia, hypotension, cardiac dysfunction and arrest.

Typically, the patient who develops significant RPE will become symptomatic within 15 minutes to 2 hours after the rapid re-expansion of the lung. Tachypnea and tachycardia are commonly associated with cyanosis and a cough productive of frothy pink sputum. Unilateral rales are found over the affected hemithorax. The patient's dyspnea and hypoxemia fail to resolve with the administration of supplemental oxygen by mask or cannula. Radiographic opacities with an alveolar filling pattern become apparent within 2 to 4 hours after re-expansion and typically persist for 4 to 5 days if the patient survives.

Treatment options are limited to maneuvers that will decrease the newly created ipsilateral intrapulmonary shunt. The quickest and simplest intervention would be to allow the lung to collapse again. This action would reduce the pulmonary artery blood flow to the alveoli without gas exchange, thus eliminating the ventilation/perfusion mismatch and shunt. Similar reduction in arterial blood flow to the affected area has been achieved by the placement of a balloon catheter

in the ipsilateral pulmonary artery. The eventual definitive intervention will be the application of positive pressure mechanical ventilation with PEEP. The re-expansion of the alveoli by this method will, of course, recreate the re-expansion and reoxygenation problems, but control of the hypoxemia becomes manageable.[4] Prompt recognition of the underlying problem is critical for a good outcome, as approximately 20% of the episodes of RPE are fatal.[5]

The predictors of re-expansion pulmonary edema involve the duration of lung collapse and the negative pressure required to forcibly re-expand a noncompliant lung to conform with the chest cavity. Human studies suggest that a lung that has been atelectatic for 3 or more days may develop edema with rapid re-expansion and reperfusion.[6] Animal data suggest a similar length of time with an incidence of RPE reaching 85% if the lung has been atelectatic for 8 days or more.[7]

Given the clinical setting of a chronically collapsed lung, the second predictor is rapid re-expansion usually by creation of relatively "excessive" negative pleural pressures. The absolute level of negative pressure that has caused RPE has varied and may not be as critical as the rate of the re-expansion.[8]

In humans, the apparent requirement for both a chronically collapsed lung and rapid re-expansion suggests that the pathogenesis of RPE can be examined in two stages: changes that occur during the time of collapse and changes that result from rapid re-expansion. Several explanations have been proposed and the etiology is probably multifactorial, involving both mechanical and chemical stresses (Table 1).

During the period that the lung is collapsed, some of the atelectatic parenchyma will have areas in which alveolar gas is completely resorbed. These areas of lung will then receive reduced pulmonary artery blood flow. Because the residual bronchial circulation will supply the small airways but not the lung parenchyma,[9] alveolar and vascular endothelial cells may be deprived of the oxygen required for continued metabolism of surfactant.[10] Any absolute or relative abnormalities in this phospholipid augments the tendency of the collapsed lung to remain atelectatic by increasing inward lung recoil pressure.

Table 1. Factors proposed that may contribute to unilateral re-expansion pulmonary edema.

- Altered surface tension resulting from abnormalities of surfactant.
- Hypoxic injury to lung microvasculature during the period of collapse.
- Mechanical stresses on the lung capillaries from the negative pressure used to reinflate the lung.
- Decreased fluid removal by the lymphatics during more negative pleural pressures.
- Xanthine oxidase activity during reoxygenation and reperfusion of tissue undergoing sublethal ischemia.

Additional biochemical changes occur during the period that the collapsed parenchyma is hypoxic. A decrease in mitochondrial oxygen utilization causes a shift to anaerobic metabolism. Under these conditions, investigators have documented an increase in two intracellular enzymes, xanthine oxidase and aldehyde oxidase, that are capable of promoting superoxide radical formation.[11] Increased extra-mitochondrial release of pronated hydroperoxyl radicals may be promoted by decreased availability of mitochondrial dismutase in tissues undergoing sublethal ischemia. Thus, after a sufficient period of collapse and hypoxia, the capillaries deprived of oxygen will have an increased permeability to protein.[8,12]

The alveolar-capillary basement membrane of the human lung is now in jeopardy of sustaining damage from the mechanical forces of rapid re-expansion as well as the biochemical changes associated with reperfusion/reoxygenation. The mechanism of vascular injury during re-expansion involves the linear stretching of the extra-alveolar vessels with increased tension on the alveolar septal walls.[13] The torque on the relatively stiff parenchyma with decreased surfactant activity results in an increased transmural pressure gradient across the pulmonary microvessels that is augmented by the elevation of intravascular pressure as pulmonary artery flow resumes.[14] This sudden imbalance of interstitial and hydrostatic forces favors a net transudation of fluid from the vasculature into the interstitium. When the lymphatic system is overwhelmed, intra-alveolar flooding occurs and an intrapulmonary shunt is established.

Histologic appearance of the parenchyma confirms intra-alveolar and perivascular edema, intra-alveolar inflammatory cells, and focal hemorrhage which are analogous to the changes seen in other acute, noncardiogenic, edematous lung injuries. The ratio of alveolar fluid protein to serum protein concentration is above 0.7, indicating increased capillary permeability.[12]

It has been estimated that atelectatic lung may require static pressures of approximately 18

Table 2. Measures that minimize the occurrence of unilateral pulmonary edema by allowing controlled re-expansion of a chronically collapsed lung.

- Removal of no more than 1200 cc of pleural fluid during a single thoracentesis.
- Avoid the use of vacuum bottles or high negative pressures during fluid removal.
- Avoid the immediate application of negative pressure wall suction after chest tube insertion for chronic pneumothorax. Employ Heimlich valve or underwater seal initially.

mm Hg more than the pressure needed to inflate normal lung.[15] Although emphasis is often placed on the amount of negative pleural pressure employed during rapid re-expansion pulmonary edema, these forces do not have to exceed those commonly employed in clinical medicine. Pleural (ie, interstitial) pressure is observed to attain the most negative values in the area of persistent collapse.[16] Re-expansion pulmonary edema has been observed in monkeys with the application of only 10 cm H20 negative pressure, provided the lung had been collapsed for 72 hours. The observation that re-expansion of the lung by tube thoracoscopy attached only to underwater seal did not result in RPE is of clinical significance.[13]

It is therefore concluded that pulmonary edema resulting from negative pressure reinflation of the lung is related more to the fact that the lung is rapidly and prematurely expanded, rather than to any absolute value of negative pressure. The occurrence of RPE after large volume thoracentesis by gravity dependent drainage supports this observation. In this situation, there is a direct correlation between the volume of fluid removed, the observed increase in hypoxemia, and the degree of RPE.[17]

In addition to mechanical forces, it is generally agreed that some of the alveolar-capillary injury occurs as a result of reperfusion in a manner consistent with hypoxia/reoxygenation injuries observed in other organs.[18] In these situations there is an enhanced reduction in mitochondrial respiratory chain components that results in superoxide production during reoxygenation. The reduced mitochondrial dismutase allows increased release of endogenous free radicals that damage the vascular endothelium resulting in leaky capillaries analogous to ARDS.[11] The accumulation of activated neutrophils in reperfused tissues may also contribute in free radical production.[12]

In summary, the frequency and severity of RPE are related to the duration of prior lung collapse and the techniques used in attempts to rapidly re-expand atelectatic parenchyma. Adoption of conservative approaches to thoracentesis and/or chest tube evacuation with suction should be encouraged when the duration of lung atelectasis is undetermined (Table 2).

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A Privilege to Serve

TO THE EDITOR: *My last address as Chairman of the Department of Pediatrics at the University of Louisville School of Medicine is submitted to be shared with the many former students, residents, physicians, and members of the KMA of which I am most proud to be a current member, having served in many capacities over nearly three decades. I have truly been privileged to serve.*

This is truly a most happy occasion. A goal has been reached. The graduates are either going on to their life's work or for more training. For some this is a sad day, too. Many will be parting a friendship spawned in the stressful crucible of residency. For me, this is the last time to speak to you as Chairman of the Department of Pediatrics and as Chief-of-Staff of the Kosair Children's Hospital. You are the 24th and last group. I think that every group is the best. You are the best. As you may know, it is a tradition for the chief resident to select my topic, possibly to help keep my comments brief. I am supposed to charge the graduates, inspire and stimulate the incoming and remaining residents, and convince the faculty of the wise choice they made of careers in pediatrics.

"A Privilege to Serve" is my subject. In the purest sense, privilege comes from the Latin, *privus*, separate, plus *lex*, a law, a special right or favor, etc, granted to some person or group. You are a special group and favored group. Serve comes from the Latin, *servire:* (1) To be a servant to, (2) To do service for, aid, help, etc. You have chosen to serve infants and children. "For unto whomsoever much is given, of him shall be much required."[1] As physicians and pediatricians you have been specially blessed and rewarded to have been selected and to have completed one of the oldest and most respected programs in our country. You are a part of a noble tradition. *Noblesse oblige:* your responsibility is to take leadership roles to assure the health and welfare of those whom you serve.

Dr Wilburt C. Davison, Dean, Professor and Chairman, Department of Pediatrics at the School of Medicine, Duke University, told all medical students "Pediatrics is the best of all specialties, for the patients we help benefit the longest." You must deal with the greatest treasures of parents and grandparents and our future. There is no more beautiful sound to the pediatrician than the cry of a previously asphyxiated infant or a child who was too sick to utter a sound, or just the parting smile or thank you from a child leaving your office or the hospital. What a great sense of accomplishment. What a wonderful reason for living. The day and world will be better for your lives.

It had not entered my mind that my confirmation statement would be fulfilled as a pediatrician. "Inasmuch as ye have done unto one of the least of these my brethren, so ye have done it unto me."[2] Even when I wrote in a poem, "Graduation Day,"[3] "Let my practice be long and sure; Let my life be of service and be pure," I did not know that I would serve as a pediatrician. Some great pediatricians who have considered their service to infants and children a privilege have also served as lamplighters of my way.

Jay M. Arena, Professor of Pediatrics at Duke University; the complete pediatrician; expert in accidents and poisoning, treatment and prevention; a great President of the American Academy of Pediatrics; and among many honors was also a Distinguished Louisville Pediatric Society Lecturer, remains an example for me as I remember the joy and fulfillment he expressed with every infant and child in his practice. I can still see his smile and hear the loving words he uttered to the patients and their parents, a pediatrician who loved to serve children.

To my great mentor at Walter Reed, Colonel Ogden C. Bruton, discoverer of agammaglobulinemia, "The patient was first and last, always, with no regard for fee."[4] What a great physician, teacher, servant!

"And whosoever of you will be chiefest, shall be servant to all."[5] Pediatricians are great servants — and are true advocates for all aspects of children's needs.

I love pediatrics. Many in the discipline and in other specialties still question and chide me about how I know God is the Great Pediatrician, a term I have used across this land and that you have all heard me use, especially in hopeless situations. *I don't know!* But God is love and pediatricians love children.

When the press unfavorably criticizes the medical profession, a favorite activity of theirs, they usually exclude pediatricians. We are not the highest paid physicians, but we are "rich in treasures in heaven, where neither moth nor rust doth corrupt."[6] We want all children to have access to quality health care, *prevention* and *treatment.* Our lives are committed to this goal.

In many physicians' offices, hospitals, schools, and other places (our Alliant Library) you may see the Children's Bill of Rights which states our responsibility to children. You have received the most quoted line, "The level of civilization attained by any society will be determined by the attention it has paid to the welfare of its infants and children."[7] Also, I would be remiss not to charge you with "The responsibility of the pediatrician is to prevent, to diagnose, to prognosticate, to treat when and if necessary, and at all times to keep foremost in mind *primum non nocere.*"[8] Mrs Jean Ashley, administrative assistant of our medical education office, and Martha Walls Oldham, my former administrative assistant, changed the statement by

substituting pediatrician for physician and started the tradition of giving it to all residents who trained here. Ross Laboratories sent it to pediatricians everywhere.

Also, let me give a final plea and urge you to use analgesics appropriately and to remember that pain does not go away immediately, even with the most potent antibiotics. It may take hours or days for pain to subside without help. Remember, "To cure a few, to help many, to comfort all. This is the good physicians call."[9]

Even with the changes brought by corporate medicine and the looming possibility of socialized medicine, pediatrics will continue to be fun, to be its own reward, and to be the happiest area of medicine. We can be justly proud of our profession.

I will close with the last stanza of "Medicine is More than a Profession."[10]

> "Medicine then is more than a profession,
> Medicine is a worthy calling, a true avocation.
> Medicine is a most magnificent obsession.
> Medicine requires all the abilities in one's possession.
> Its influence on life's and death's progression
> Makes medicine more than a profession."

You should be proud of your privilege to serve infants and children. It has been a joy and privilege for me to serve you as professor and chairman. Rest assured that I will continue to help and serve you and children in every way possible as long as I can. God speed you in your life's work. Thank you.

Billy F. Andrews, MD
FAAP, FACP, FRSM
Professor and Chairman
Department of Pediatrics

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RDW

RDW. Is this someone's initials, a new radiographic test, or perhaps a new medicine? This may seem odd but the matter came up recently during the middle of the night. I was awakened with a phone call giving me the results of a complete blood count I ordered on a patient. I listened for the hemoglobin and hematocrit values, which were my main concern. Before I could say "thank you," the nurse began reading the remaining values which come with a complete blood count. What could I do but politely listen? I sounded like Ray Charles, as I muttered "Uh-huh" after each value. Unfortunately I had forgotten how to apply most of these values to the care of my patient. As a result of this, I felt compelled to learn how to use the RDW. Who knows, I might even be able to use it some day!

The red cell distribution width, or RDW, is an index of red blood cell size difference, often called anisocytosis. Normally, most red blood cells are approximately equal in size, but certain disease states can change their size. This could be by fragmentation, like in hemolysis, or a gradual process of size change in newly produced red blood cells. The RDW can be elevated or normal, but can never be decreased. The RDW is sometimes abnormal before the anemia appears and may even be abnormal before the mean corpuscular volume.

Table. Red Blood Cell Distribution Width and Mean Cell Volume

*NL*RDW, low MCV*	*NL RDW, NL MCV*	*NL RDW, high MCV*
Thalassemia minor	Chronic disease (90%)	Aplastic anemia
Chronic disease (10%)	Hb AS, AC	Myelodysplastic syndrome
	Hb AS, AC	Alcoholism
	Hereditary spherocytosis	
	Acute bleeding	
	Cirrhosis	
	Uremia	
High RDW, low MCV	*High RDW, NL MCV*	*High RDW, high MCV*
Iron deficiency	Early factor deficiency	B12 or folate deficiency
S-thalassemia	SS disease†	Autoimmune hemolytic anemia
Hb H	SC disease‡	Cold agglutinins
RBC fragmentation	Myelofibrosis	Newborn
	Sideroblastic anemia	

*NL, normal.
†SS disease means that sickle hemoglobin (Hb S) is present on both genes (SS).
‡SC disease means that one gene for Hb S is combined with one gene for Hb C.

Clinical Laboratory Medicine, 5th ed.
Richard Ravel, Copyright 1989,
Yearbook Medical Publishers, p 13.

William P. Hoagland, MD

THE JAMES...THE NEXT GENERATION OF HOPE



OUR AREA OF EXPERTISE COVERS A LOT OF GROUND.

Cancer crosses all cultures and all nationalities without exception. So it stands to reason that the treatment and eventual cure of a condition experienced worldwide would require talent and intellect from around the globe.

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Interprofessional Code

Kentucky Medical Association and Kentucky Bar Association

The Physician-Attorney Liaison Committee, composed of members of the Kentucky Medical Association and the Kentucky Bar Association, met in January at KMA. The Committee reviewed the Interprofessional Code, last revised in October 1984, and agreed to publish the Code in this issue of The KMA Journal *and the spring issue of KBA's* Bench and Bar, *soliciting comments and suggestions from members of each profession on how the Code might be revised to more effectively deal with specific problems or concerns physicians and attorneys might have in their dealings with each other. Suggestions for revisions to the Code and comments should be addressed to the Kentucky Medical Association, 301 N Hurstbourne Parkway, #200, Louisville, KY 40222, Attention: Physician-Attorney Liaison Committee.*

The Committee is also exploring ways to further improve the relationship between attorneys and physicians. Suggestions made at the meeting included encouraging joint informal meetings of local bar and medical associations, participation by members of one profession in seminars on subjects of interest to the other profession, and guest articles in each association's professional publication. Anyone interested in pursuing such opportunities or suggesting others is also encouraged to contact KMA.

The Committee plans to meet again in May to consider revisions to the Interprofessional Code and suggestions from each association's membership.

Preamble
Revised October 16, 1984

General Principles

Doctors of medicine and attorneys at law, as members of two professions possessing a close personal relationship with those they serve, have established principles of ethics applicable to the traditions and requirements of their respective callings.

The physician has responsibility for the care of the individual, in health as in disease. He must minister to his patient's needs to the best of his ability and in accordance with the high precepts of the Hippocratic Oath.

The attorney is an officer of the court, sworn to support the Constitution of the United States and of the state or states in which he is admitted to practice. As is the physician, he also is pledged to maintain the confidence and to preserve inviolate the secrets of his clients. He will not reject, from any consideration personal to himself, the cause of the defenseless or oppressed, nor delay any man's cause for lucre or malice.

The attorney represents his client as advisor and confidant, as his advocate in legal proceedings and as negotiator in the business and personal affairs of his client. The physician's relationship is parallel, for he is also the advisor and confidant of his patient in matters of health.

Interprofessional Relations

Each profession is obligated by its own stature to respect and honor the calling of the other. Neither the fact nor the appearance of incompetence, corruption, dishonesty, or unethical conduct on the part of individual members of either profession can be tolerated. It follows then that each profession must vigorously support within its own ranks, as well as in the ranks of the other, those ethical concepts which each has found necessary in the public good. One who has chosen to be a physician or an attorney and has been found competent to be such by appropriate authorities, is vested with high responsibilities and privileges to enable him to serve the public with honor, with dignity, and with effectiveness.

This Code

A statement of ethical principles states a guide to the attainment of the best in interprofessional conduct and practices. IT IS NOT NECESSARILY OF A BINDING CHARACTER, NOR CAN IT BE SO DETAILED TO COVER EVERY CIRCUMSTANCE.

This Interprofessional Code constitutes the further recognition that with the great developments in the science and art of both medicine and law, it is inevitable that the physician and the attorney are drawn into steadily increasing association, as the law calls with increasing frequency upon medicine for its scientific knowledge and for its evaluation of facts so that the rights of

individuals and of the government may be appropriately determined before various tribunals.

I. RECIPROCAL DUTIES

A. The Attending Physician and His Patient

The medical profession affirms the obligation of a patient's attending physician to cooperate willingly with the patient's attorney in supplying facts, primarily available only to him. The physician should accept the further responsibility of explaining such facts in such a manner that the attorney understands them and can determine their relationship to his client's cause. There should be complete cooperation between the physician and the attorney, each assuming his proper responsibility.

It is for the physician to determine the actuality or probability of fact pertaining to his patient's medical condition. It is for the attorney to determine how and under what circumstances such facts are to be appropriately presented.

A physician should never advise on the amount of damages a patient should seek to recover. The proper province of his professional advice is the extent, degree, or percentage of illness, injury, disability, or similar judgments based upon his professional knowledge of the case. He is not expected to understand technical rules of legal liability, or evidence, or of trial techniques. The latter are the exclusive province of the attorney.

B. The Attorney and His Client

It is a part of the attorney's oath on his admission to the bar of this state that he will not counsel or maintain any suit or proceeding which shall appear to him to be unjust, or any defense, except such as he believes to be honestly debatable under the law of the land. He will employ, for the purpose of maintaining the causes confided to him, such means only as are consistent with truth and honor and will never seek to mislead the judge or jury by any artifice or false statement of law or fact.

In discharge of that oath, it becomes the attorney's responsibility to marshal the facts and to obtain professional and other opinion which, in his judgment, are necessary for his client's case and in a manner consistent with his oath and the ethics of his profession.

It is important that the physician understand that legal proceedings in this country are conducted under what is known as the "adversary system." Under that system the attorney occupies a dual position. He is not alone an officer of the court. He is also the single-minded advocate for his client. He does not and cannot properly represent both sides to a dispute.

This system has developed in recognition of the truth demonstrated countless times that justice can usually be satisfactorily accomplished if the two or more contestants can present their point of view to some neutral third person who can weigh the opposing claims. Such claims are usually presented in the form of testimony which is offered in question and answer form. The judge of a court of the officer presiding before an administrative tribunal is the referee who weighs the opposing points of view and the conflicts in testimony. In a sense the judge or administrative officer much more nearly approximates the physician in objectivity. The physician well knows, however, that in some situations it is also possible for medical men to vary honestly and sincerely in their physical findings, their treatment, and their evaluation of illness or injury. In some types of court cases the parties prefer to let a group of sworn but interested citizens, the jury, weigh and "find" the facts.

II. MEDICAL EXAMINATIONS

(Requested by Attorneys or ordered by Court)

A. General

1. The law provides that a party to a lawsuit may be required to undergo a medical examination by agreement of the opposing attorneys or under a court order.

2. When an appointment is made for the medical examination of a person, the physician sets aside a part of his day for that purpose. It is, therefore, important that attorneys exert their best efforts to insure that such appointments are kept. The attorney for the party to be examined should give explicit instructions to such party that the physician must be notified in ample time should it become impossible for the party to keep the appointment.

B. Scope of Examination

1. The physician may take a history and perform such examinations as may be advisable in his judgment to formulate an informed opinion regarding the nature and extent of the party's medical condition.

2. Inquiries should not be made by the physician into matters not reasonably related to the legitimate scope of the medical examination.

3. The physician, following his examination, shall reduce to writing a medical report, following the outline set forth in Section III.B.5. herein. The original report shall be forwarded to the court or person requesting the examination, with copies as directed by the court or by the person requesting the examination.

III. WRITTEN MEDICAL REPORTS

(Prepared for Courts or Attorneys)

A. The Attorney

1. Requests for reports from a physician should be made in writing as soon as it is known that the information is needed. The request should be clear as to the specific information desired and the report should be prepared by the physician as promptly as possible.

2. If a report is requested on a physician's patient, the attorney must provide the physician with a written authorization from the patient.

B. The Physician

1. **Medical Records.** The physician must keep records adequate to supply a patient's attorney all pertinent information regarding the patient-client's medical history.

2. Requests for medical reports should be honored promptly. Undue delays in providing medical reports of bills bearing on a patient's legal rights may prejudice his case.

3. If a physician is unable to make a complete medical evaluation within the time required, he should notify the attorney. In this event, a preliminary report clearly designated as such may serve the attorney's needs until a complete evaluation can be rendered.

4. Patient's Authorization. The physician must have his patient's written authorization before releasing any report or test concerning the patient. Such authorization is not necessary when the person examined is not a patient of the physician, and the examination is made in connection with a legal claim.

5. **Content of Report.** The following, where applicable, should be included in the report:

a. Time, date and place of first visit.

b. Accurate history of the injury or medical condition, including pre-existing disease or prior injury.

c. Nature of examination and findings.

d. Results of laboratory work, x-rays, and consultations.

e. Opinion including, where possible, diagnosis and prognosis. **Upon request,** the opinion should also evaluate future physical impairment, necessity for future treatment or surgery, the effect of aggravation of any pre-existing disease or prior injury, and length of convalescence. The opinion should likewise include the physician's true opinion on the cause of the patient's condition, and the strength of his opinion in evaluating the cause. In this regard, he should consider and state all objective and subjective matters bearing on this opinion, including, where appropriate, his evaluation of the patient's candor when considered in the light of his own medical knowledge.

f. State if patient's condition is stationary, or if the patient is discharged.

g. Subsequent examination: Include complaints and evaluation of condition, nature of treatment, confinement to hospital or home, referrals to other physicians, patient's progress, results of x-rays, ECGs, EEGs, laboratory work and consultations, and a concluding diagnosis and prognosis (see Item e, above).

h. Enclose separately an itemized statement of medical expense to date. Omit charges for medical reports or attorney consultations or ANY REFERENCE TO INSURANCE.

i. Include estimate of cost of future medical care.

IV. CONFERENCES

The physician and the attorney should confer relative to the common problems presented in a particular case. Such conferences should be arranged well in advance of court or other hearing at the mutual convenience of each, in full appreciation that to each profession, time is of the utmost importance. No physician and no attorney should be required to spend unnecessary time in arranging or attending such a conference. The attorney who knows and understands the progress of his client's case, the conflict, if any, of its medical aspects and the probability of settlement or trial should determine the necessity of a conference.

It is unfair to the patient-client, the physician, and the cause of justice to present a medical witness who has not first conferred with the attorney and who, therefore, may lack a full appreciation of the significance to the case of the particular evidence he is being asked to give. It is equally obvious that the attorney is less able to represent the full interest of his client where he has not had the advantage of full conferences with the physician in advance of presenting the case.

V. DEPOSITIONS AND/OR COURT APPEARANCE

Our system of justice depends on being able to require any citizen's time at a judicial proceeding and to give testimony regarding the case. A conference should be held between the physician and the attorney proposing to call him as a witness at some time mutually convenient before the physician is to testify.

A. Court Testimony

Both parties recognize that when it has been determined that the just and proper effect of a physician's testimony cannot be obtained without an oral examination in court, there is a necessity for the dissemination of information of both professions concerning the time problems involved in court testimony. The Medical Association recognizes that the legal profession faces calendar problems, which include the uncertainty of dates in a fluid trial calendar. The Bar Association likewise recognizes that the physicians appointments are made in advance and that physicians are in addition faced with pressing medical problems which sometimes cannot be deferred.

1. Attorney's Duties:

a. The attorney should ascertain whether the physician will be available for a trial term prior to the date assigned for trial at that term. He should not order the attendance of a physician as witness unless necessary and in any case without prior notice and conference concerning the matters as to which he is to be interrogated unless both the attorney and the physician agree that such conference is unnecessary.

b. The attorney should write to the physician immediately following the docket call to advise the physician of the proposed trial date.

c. The attorney should keep the physician's office advised of the sta-

tus of the docket and notify the physician as soon as possible prior to trial of the probable trial date.

d. In the event of settlement or postponement, the physician should be immediately notified of that fact.

e. The attorney should give the physician as much notice as possible of the time when his attendance in court is desired. Physicians should not be asked to appear until the attorney is reasonably certain that they will not have to remain at the courthouse more than a short period of time before being allowed to testify. When the physician enters the court room, he shall, through a court attendant, make his presence known to the attorney trying the case. The attorney shall endeavor to put the physician on the stand as soon as possible after his arrival in the court room subject to orderly and proper presentation of the case.

2. **Physician's Duties:**

a. The physician has a moral and ethical obligation to give testimony regarding his patient. If the physician undertakes the care of a patient and litigation ensues, the physician should recognize his responsibility to testify as to the medical condition of that patient, subject to the provisions of the Agreement.

b. When given adequate notice of the time when he will be called upon to testify, the physician should make himself available at that time, unless an emergency situation arises which precludes his appearance.

B. Depositions

1. **Physician-Patient Privilege.** Where testimony is given and documents are called for by counsel during the taking of depositions in personal injury lawsuits, the usual obligation of confidence in the physician-patient relationship does not exist, and physicians shall furnish any and all pertinent documents, reports, records, notes or x-rays regarding the patient which are requested by counsel for either party to the lawsuit.

2. **Deposition Defined.** A deposition is an official proceeding authorized by law whereby a physician may be required to give testimony and be cross-examined under oath outside of court before a court reporter who is a notary public and in the presence of attorneys representing the parties. He may be requested to produce pertinent medical records at the deposition hearing. He may also be requested to release the records, x-rays, ECGs, EEGs, etc to the notary public for duplication and return.

3. **Time and Place.** The time and place of the deposition should be set **by agreement** with the physician. Unless there is a compelling reason to the contrary, it should be taken at the physician's office **at the time agreed, keeping in mind that an attorney's time has the same value as a physician's.**

4. **Subpoenas — Medical Records.** Production of pertinent medical records may also be required by subpoena duces tecum served on the physician. That subpoena requires the physician to attend the deposition at the time and place stated in the subpoena, and there to produce the specified records.

5. **If Attendance at Deposition a Hardship.** If the time and place described in the subpoena for the deposition creates a hardship, the physician should immediately bring this fact to the attention of counsel taking the deposition.

6. **Preparation and Deportment**

a. The Physician. Since the testimony given at deposition hearings may be read at the trial, it is important that the physician prior to deposition prepare himself as for trial and that his attitude and deportment at the deposition hearing be similar to that at trial.

b. The Attorney. An attorney should totally prepare his case from the medical-legal standpoint so that with a careful use of words he can reduce the area of misunderstanding. It is not proper for an attorney to seek to color the professional opinion of the physician. No attorney is justified in abusing, badgering or brow-beating any witness, including a physician.

7. **Familiarity with Records.** The physician and the attorney should be thoroughly familiar with their own records and with other related records, including hospital charts and records, at the time the deposition is taken and should have as many of the records at the time the deposition is taken as is possible so that they may be referred to as needed.

8. **Predeposition Conference.** It is to be understood that it is proper to have a predeposition conference between the attorney for the patient and the physician to facilitate the taking of the deposition.

NOTE: If court testimony or a deposition of a physician cannot be set by agreement, the physician's attendance can be required by appropriate legal process. If any doubt arises as to the effect of such legal process, the physician should consult his attorney. A physician should not take offense at being served with a subpoena in the event an agreement cannot be made.

VI. COMPENSATION FOR MEDICAL REPORTS, DEPOSITIONS, COURT APPEARANCE AND OTHER SERVICES

It is impractical to establish precise rules governing a physician's fees for medical reports, reviewing medical records, conferences, opinions, depositions, court appearances, copies of medical records and other services. It is important, however, that fees be reasonable and that they be discussed in advance by the physician and the attorney. In this way, the major cause of misunderstanding and dissatisfaction will be eliminated. Generally, the attorney who requests these services of a physician is primarily responsible for prompt payment of the physician's reasonable fees. **Under no circumstances may a physician charge a fee for such services which is contingent upon the result of the lawsuit.**

As a matter of policy an attorney should not request a physician to testify on deposition or in court, nor should he subpoena him, without making arrangements for reasonable compensation. This is not required by law, but is suggested as a matter of fairness and cooperation between the professions. A physician should be compensated for the time spent away from his professional practice, regardless of whether he is used as a witness.

VII. COMPENSATION FOR MEDICAL TREATMENT TO THE PATIENT

A. The patient, not his attorney, is responsible for paying all bills incurred by the patient for his medical care. While bills should be sent to the attorney on the attorney's request, this does not make the attorney responsible for their payment.

B. When the attorney first obtains a written authorization from his client for the release of medical information, the attorney should request his client to authorize the attorney to take out of the proceeds of any recovery by way of settlement or verdict the funds necessary to pay the physician's then outstanding bill for medical treatment. Upon such authorization being given, the attorney should so inform the physician. Upon recovery, if any, the attorney should, in every case, seek to protect the interest of the physician and see that the physician's bill is paid. In the event there is no recovery, or the recovery is insufficient to pay the bill, the attorney should so inform the physician. (For suggested form, see Appendix A.)

VIII. IMPLEMENTATION OF THE CODE

The purpose of this Code is to establish, maintain and perpetuate a greater degree of understanding and ethics between the respective medical and legal professions. Any abuse of this Code or violations thereof by a member of either profession should be brought to the attention of the Physician-Attorney Liaison Committee for a determination to be made as expeditiously as possible.

Notice of the nature and pendency of the complaint shall be given to the person about whom the complaint is made.

IX. AMENDMENTS

This Code may be amended from time to time upon joint resolution of the respective associations represented herein.

This code was originally implemented by a joint committee of the Kentucky Bar Association and the Kentucky Medical Association in 1973.

The revised Interprofessional code was approved in 1984 by the KMA House of Delegates and the Board of Governors of the Kentucky Bar Association.

APPENDIX A
AGREEMENT TO PAY PHYSICIAN FEES

I, _____

hereby authorize and direct my attorney, _____, to pay promptly to _____, MD, from my portion of the proceeds of any recovery which may be paid to me through my attorney as a result of the injuries sustained by me (and _____), on _____, 19____, the unpaid balance of any reasonable charges for professional services rendered by said physician and his associates on my behalf, said professional services to include those for treatment heretofore or hereafter rendered to the time of the settlement or recovery, as well as those for medical reports, consultations, depositions and court appearances on my behalf. I understand that this does not relieve me of my personal responsibility for all such charges in the event there is no recovery or if the recovery is insufficient to satisfy such charges.

DATED _____

Patient _____

APPROVED AND ACCEPTED:

DATED _____

Attorney _____

YOCON®
YOHIMBINE HCl

Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

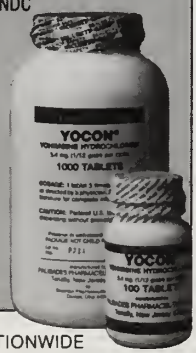
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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AKMA Annual Convention



Beryl Dodds

Spring in Kentucky means blooming flowers and trees. It also means it's time for the AKMA Annual Convention. We are meeting this year in Madisonville, April 19-21. Members of the Hopkins County Medical Auxiliary are anxious to share their hospitality with fellow members of the Auxiliary to the Kentucky Medical Association. We invite you to come and be a part of our celebration as we share the accomplishments of this year and make the transition to a new year.

Our guests for this meeting will be Nancy Evans, AMA Auxiliary Treasurer; Ebba Dunn, SMA Auxiliary President; and Dr William Monnig, KMA President, who will speak at our installation dinner.

Our House of Delegates will meet at the Fine Arts Center located on the campus of Madisonville Community College. This is a beautiful facility and we look forward to sharing it with you. On exhibit during the month of April will be "The Shakers — Their Work, Art, and Music." This exhibit is from Shakertown in South Union, Kentucky.

A highlight of our meeting will be the installation of our new officers. They will be installed by AMA Auxiliary Treasurer, Nancy Evans. The 1993-94 AKMA officers are:

President
Gloria Griffin, Jefferson County

President-Elect
Joyce Clark, Pulaski County

First Vice President
Marla Vieillard, Boyd County

Central Region Vice President
Nancy Swikert, MD, Northern Kentucky

Eastern Region Vice President
Gwyn Parson, Pulaski County

Western Region Vice President
Mary Jo Bauer, Hopkins County

Recording Secretary
Marna Loucks, Daviess County

Treasurer
Betty Housman, McCracken County

This is a very sensitive time for medicine. Changes are being made in health care delivery which will forever effect the quality of medical care available not only in Kentucky but across the country. As the spouses of physicians, we can and should be very active as advocates for medicine. We can do this by working in community health projects (including working with and for child and spouse abuse shelters to help stem the tide of family violence), by working for improved health education curriculums in our schools, and by working for effective health care legislation. We can also show our support by being members of the Auxiliary to the Kentucky Medical Association.

Helen Keller once said, "I can't do everything, but I can do something. I will not refuse to do the one thing I can."

As the spouse of a member of the Kentucky Medical Association, you can make a difference by joining the Auxiliary to the KMA. Send a check for $40 to Jean Wayne, AKMA, 301 N Hurstbourne Pky, Suite 200, Louisville, KY 40222-8512.

"This is a very sensitive time for medicine. . . . As the spouses of physicians, we can and should be very active as advocates for medicine."

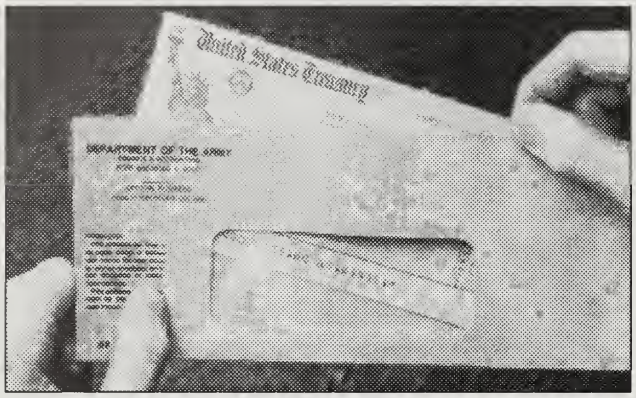
Join us in Madisonville April 19-21 as we share our accomplishments and plan for the future. TOGETHER, WE CAN MAKE A DIFFERENCE AS WE WORK TODAY FOR A BETTER TOMORROW.

Beryl Dodds

AKMA President

ANESTHESIOLOGISTS AND SURGEONS: COULD YOU USE AN EXTRA $9,000?

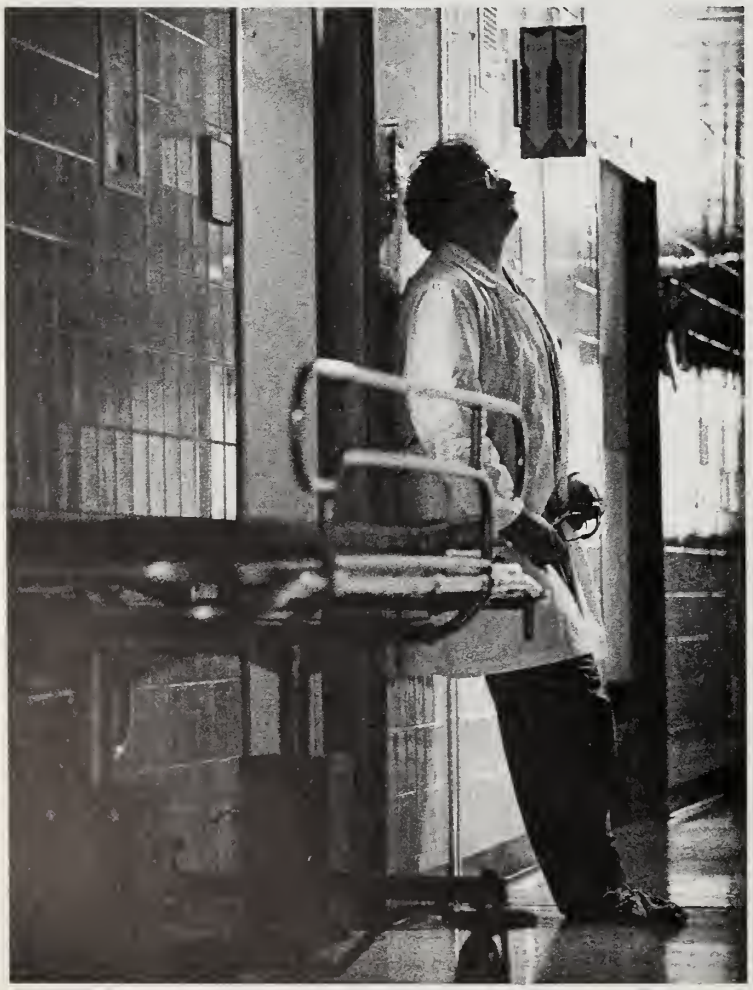
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Dr. Kevin Fullin, Cardiologist, Kenosha, Wisconsin,
Member, American Medical Association

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"Fully a third of all women's injuries coming into our emergency rooms are no accident," says Dr. Fullin.

While others were content to downplay the issue of family violence, Dr. Fullin would not. He petitioned state officials, and through his efforts the first Domestic Violence Advocate Program in his state was created.

"Organized medicine must serve as an advocate for patients," stressed Dr. Fullin.

The American Medical Association (AMA) couldn't agree more. We're committed to focusing physician attention on the issue of family violence.

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Members of the AMA are encouraged to join their state, county and specialty societies.

American Medical Association

Physicians dedicated to the health of America

1993

APRIL

16-17 — Office Endocrinology; Hyatt Regency; French Quarter Suites, Lexington, KY. 11 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

MAY

1-7 — Advances in Family Medicine course, sponsored by the Department of Family Medicine of the University of Cincinnati; Albert B. Sabin Convention Center, Cincinnati. Contact: UC Department of Family Medicine, 513/558-4021.

7-8 — Contemporary Pediatrics: Hyatt Regency, Lexington, KY. 9.5 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

7-8 — The Virginia Society of Otolaryngology-HNS Annual Meeting; Tides Inn Resort, Irvington, VA. Contact: Donna Scott, 4205 Dover Rd, Richmond, VA 23221; 804/353-2721.

13-16 — Central Atlantic Seminar in Anesthesiology; Washington, DC. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037, 202/994-4285; FAX 202/994-1791.

20-22 — The American Society of Internal Medicine Leadership Development Conference; Mariott Hotel, Portland, Oregon. Contact: Melinda Klein; 202/835-2746, ext 266.

23-28 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

JUNE

10-12 — 38th Great Smoky Mountains Pediatric Seminar; Park Vista Hotel, Gatlinburg, TN. Contact: CME, 1924 Alcoa Highway, D-116, Knoxville, TN 37920; 615/544-9190.

SEPTEMBER

18 — Tenth Annual Ophthalmology Seminar: Update on Management of Age-Related Macular Degeneration; Humana Hospital Audubon, Louisville, KY. Contact: Cathy Edens, 240 Audubon Medical Plaza, Louisville, KY 40217; 502/636-2823.

KENTUCKY ACADEMY OF FAMILY PHYSICIANS

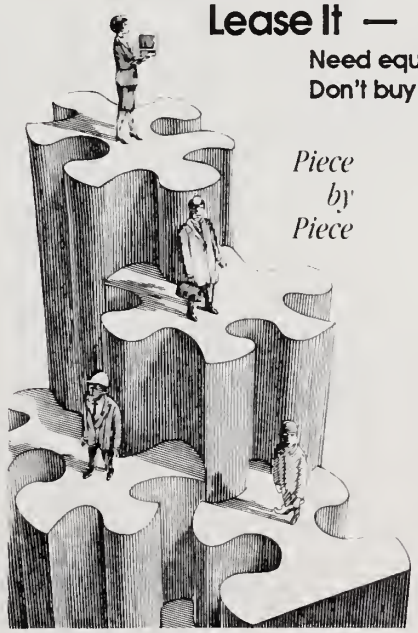
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OCTOBER

13-17 — The American Society of Internal Medicine 37th Annual Meeting; J. W. Marriott Hotel, Washington DC. Contact: Melinda Klein; 202/835-2746, ext 266.



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❒ YES I wish to join PAWH in the struggle to end world hunger – enclosed is my contribution.

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CITY STATE ZIP

SIGNATURE

Please forword your tax deductible contribution to
Physicians Against World Hunger
#2 Stowe Rood, Peekskill, NY 10566

PEOPLE

David Robertson, MD, emergency medicine, University of Kentucky, recently won Best of Show and Best Color in the Kentucky Moments exhibition, a visual arts exhibit created by the Frankfort Arts Foundation to celebrate the work of Kentucky photographers.

Arthur H. Keeney, MD, Louisville, was recipient of the Statesmanship Award at the Joint Commission on Allied Health Personnel in Ophthalmology (JCAHPO) annual reception held in Dallas, Texas. The Statesmanship Award is JCAHPO's recognition of outstanding achievement in and for the health science of ophthalmology. It is conferred once each year to a deserving commissioner. Dr Keeney has held many leadership roles in JCAHPO including President in 1988. He is currently President of the JCAHPO Education and Research Foundation. As a commissioner, Dr Keeney represented both the American Medical Association and the American Ophthalmological Society. He also lectures at several JCAHPO annual continuing education programs.

Mary A. Henry, MD, was named a 1992 Distinguished Honoree during the Archdiocese of Louisville Salute to Catholic School Alumni.

Steven Lichtenstein, MD, a Louisville pediatric ophthalmologist, has been elected to the First Edition of *Two Thousand Notable American Men.*

Sam D. Weakley, MD, was included in the University of Louisville Alumni Service Award winners for 1992. The association honors alumni who have provided exceptional volunteer service to the University.

The scientific poster presentation "Cardiac Arrhythmias and Arterial Desaturation During Routine Performance of Flow-Volume Loop" won the Second Place Achievement Award in the Chest Diseases Section of the Scientific Exhibit and Poster competition held during Southern Medical Association's 86th Annual Scientific Assembly in San Antonio, Texas. KMA members included among the winning presenters were **Cheryl L. Fields, MD, Thomas M. Roy, MD, and Miguel A. Ossorio, MD.**

David A. Casey, MD, a psychiatrist, was recipient of the University of Louisville's Lawrence-Grever Award for 1992. Named in honor of Dean David Lawrence and in memory of Arnie Grever, the Award honors an alumnus who served in student government and who has since made a significant contribution to the community.

UPDATES

Rules of Order for House of Delegates

As a reminder, the 1992 KMA House of Delegates adopted Resolution U — Change of Rules of Order. Davis' *Rules of Order* replaced Sturgis' *Rules of Order* as the official code of parliamentary procedures for KMA, effective September 17, 1992.

An official copy of Davis' *Rules of Order* may be ordered from the AMA by calling 1-800-621-8335. The order number is OP999092CL. A copy is $22.50 for members and $24.95 for nonmembers.

Greater Communication Improves Physician-Patient Relationship

In each of its annual reports to the House of Delegates for the last few years, the KMA Judicial Council has cautioned physicians to do what they can to enhance communication with their patients. The message bears repeating because every year the Council is called upon to resolve frequently recurring situations that may have been ameliorated or entirely avoided if there had been adequate dialogue between the physician and the patient (or in some cases, the patient's family).

This dialogue with the patient involves two parties talking and listening to one another. Particularly in the initial physician-patient encounter, the patient must be allowed to transmit crucial information to the physician as the basis for diagnosis and future course of action. Yet, according to recent health care research, doctors on average interrupt patients within the first 18 seconds of an interview, and spend less than two minutes of a 20-minute session imparting information. Consequently, 60% of patients leave the physician's office confused. Patients want a chance to tell their story. If they are denied this opportunity, it may be perceived as an assault on their dignity. It is the patient's perception of the physician's ability or willingness to communicate that will affect the patient's overall perception of the quality of care being rendered.

This situation may be exacerbated when there is an unfavorable result. It is often difficult for the patient to understand that a bad result does not necessarily imply negligence. Often a frank discussion of the problem within a reasonable time can alleviate the patient's confusion and distrust. The Judicial Council would remind physicians that patients seek sensitivity, honesty, and compassion from their doctor. Effectively communicating these qualities to the patient can enhance treatment and forestall complaints.

Guidelines on Gifts from Industry

The KMA Judicial Council considered Ethical Guidelines on Gifts from Industry issued by the American Medical Association (AMA), particularly as they relate to gifts to charitable organizations on behalf of physicians participating in a meeting or on an advisory panel. It was the opinion of the Council that such a donation would not be unethical if the following conditions were met:

1. Each individual must determine the substantiality of the donation based on the amount of services provided.
2. The donation must be predetermined by the industry providing the gift, and may never be made in response to a previous commitment between the physician and the charity.
3. The gift must not influence the physician's position on a particular product's qualifications in any way.
4. The physician must provide an actual service, such as speaking or consulting, as opposed to merely attending a seminar.

Diabetes Index Reveals Disparities

According to a report from the Kentucky Affiliate, Inc, of the American Diabetes Association (ADA), a new measure of diabetes care indicates that people in Kentucky appear to have an adequate chance for receiving needed care and services for diabetes. Kentucky's ranking of 16th in the first *Diabetes Index* reflects some of the positive *and* negative aspects of the vital resources needed for Kentuckians with diabetes.

The *Diabetes Index* was commissioned by the ADA to provide a state-by-state assessment of probable access to health care services. Results were released recently by the Kentucky Affiliate and the Kentucky Department of Health.

Kentucky received its highest score in the *services/programs* category, which includes the services and programs available for diabetes care, education, and intervention. Kentucky's most serious deficit was in methods of financing category, such as the availability of financial assistance in obtaining diabetes care, programs, and services.

"The deficits we see in access to diabetes care identified by the *Diabetes Index* will serve as a guide for ultimately increasing and improving programs and services to the residents of Kentucky," said **Russell Hoffman, MD,** president of the Kentucky Affiliate Board of Directors. "We have shared the information in the *Diabetes Index* with many of the health care providers, policy makers, and others concerned about diabetes care in Kentucky," Dr Hoffman said. "We hope that this will open some eyes to the needs of diabetes patients in our state."

The *Diabetes Index* measured states' resources in five categories: state policies, funding practices, services (such as educational and outreach programs), health care providers, and facilities offering diabetes care. According to the association, the availability of these resources can indicate how accessible diabetes care is in a particular state.

"While some states clearly rated higher than others, even the top ranking states have room to improve," said **Rice C. Leach, MD,** Kentucky Commissioner of Health. "Untreated and unmanaged diabetes can lead to life-threatening complications; access to these important resources is more critical for our residents than with most chronic diseases."

The interdisciplinary health care team may include primary care physicians, nurses, dietitians, endocrinologists, ophthalmologists, and exercise specialists.

For more information, call the Kentucky Affiliate at 1/800/766-1698 or 502/589-3837.

Help for Diabetics

Diabetics often cannot feel foot pain because of vascular problems or nerve damage. That lack of feeling can lead to problems requiring amputation.

Thomas J. Wieman, MD, a University of Louisville surgeon uses computers to detect problems before such drastic measures become necessary. Dr Wieman evaluates patients' foot pressure by having them walk on a computerized sensor mat. A color-coded image of the foot enables him to spot areas at risk and head off problems that could lead to amputation.

CME Seminar Scheduled for April

The KMA CME Committee will sponsor its 3rd Annual Seminar on the continuing medical education accreditation process on April 28, 1993, at the Holiday Inn Hurstbourne, Louisville, from 9 AM to 3:30 PM. Cost of $50 covers continental breakfast, lunch, and seminar materials. Designed for physicians and nonphysicians involved in the design and/or implementation of CME for physicians, this program will benefit CME directors, program administrators and staff, physician CME chairpersons, CME committee members, and university and medical center CME program directors and staff. To attend, contact the KMA Headquarters Office at 502/426-6200.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Allen

Mark S. Weis, MD — GP
2860 New Glasgow Rd, Scottsville 42164
1991, U of Kansas

Boyle

Larry Scott, MD — PD
303 S 4th St, Danville 40422
1973, U of Louisville

Fayette

Linda R. Ballard, MD — EM
3405 Pepperhill Dr, Lexington 40502
1979, U of Louisville

Mark W. Rukavina, MD — EM
1349 Cooper Dr, Lexington 40502
1982, Louisville State, Shreveport

Roberta L. Schaffner, MD — P
836 Euclid Ave, #6, Lexington 40502
1986, Loma Linda U

Scott Stevens, MD — R
1445 Lakewood Dr, Lexington 40502
1983, Duke U

Thomas M. Waits, MD — ONC
1221 S Broadway, Lexington 40504
1986, U of Louisville

David P. Wood, Jr, MD — U
2205 Lakeside, Lexington 40502
1983, U of Michigan

Floyd

Kenneth T. Grimes, MD — R
Rt 1428, Box 910, Martin 41649
1976, U of Guadalajara

Jefferson

Cheryl T. Adams, MD — PD
9431 Westport Rd, Louisville 40241
1980, Meharry Med Col, Nashville

Bruce R. Barton, MD — PS
419 Mallard Creek Rd, Louisville 40207
1980, Johns Hopkins

Jacob Blum, MD — FP
4603 Spring Branch Ct, Louisville 40241
1982, Memorial U, Newfoundland

Rhonda K. Buttleman, MD — PD
2707 Tucker Rd, Louisville 40299
1989, U of Louisville

Joseph F. Catalano, MD — ORS
410 Mockingbird Valley Rd, Louisville 40207
1986, Robert Wood Johnson Med Sch, NJ

Laura D. L. Clark, MD — AN
PO Box 714, Pewee Valley 40056
1981, U of Louisville

Glenn B. Davis, MD — FP
1176 Whetstone Way, Louisville 40223
1982, U of Louisville

Lawrence L. Geller, MD — U
3603 Trail Creek Pl, Louisville 40205
1987, U of Louisville

Richard L. Goldwin, MD — R
UL — Diagnostic Radiology, Louisville 40292
1973, U of Bologna, Italy

David S. Hemmer, MD — AN
57 Indian Hills Tr, Louisville 40207
1977, U of Kentucky

Mary Jane Hoben, MD — AN
233 E Gray, #612, Louisville 40202
1988, U of Louisville

William O. Lacy, MD — PUD
1202 Everett Ave, Louisville 40204
1986, U of Louisville

Rebecca Layton, MD — AN
1713 Trevilian Way, Louisville 40205
1988, U of Kentucky

Martin D. Mark, MD — GE
4001 Dutchmans Ln, #4D, Louisville 40207
1979, U of Cape Town, South Africa

Sandra J. Nairn, DO — PD
6811 Steeprun Rd, Louisville 40241
1985, Philadelphia Col of Osteo Med

Joseph C. Parker, Jr, MD — PTH
530 S Jackson, #C1C28, Louisville 40202
1962, Med Col of Virginia

M. C. Lyne Seldon, MD — FP
2100 Indian Chute, Louisville 40207
1980, U of Toronto

JoAn LeGree Shemwell, MD — IM
1169 Eastern Pky, #2343, Louisville 40217
1981, Tulane U

Randall L. Wright, DMD — DENT
2016 Woodbourne Ave, Louisville 40205

Lawrence

Samir I. Kreit, MD — S
Humana Hospital Louisa, Louisa 41230
1976, Damascus U, Syria

Madison

Lisa A. Hogan, MD — S
PO Box 445, Berea 40403
1986, U of North Carolina

Northern Kentucky

Sharon Fowler, MD — PD
7230 Cascade Dr, Florence 41042
1986, U of Cincinnati

Whitley

Theodore J. Goldbloom, MD — P
2 Trillium Way, #300, Corbin 40701
1957, U of British Columbia

Paul Moody, MD — PD
1400 Cumberland Falls Hwy, Corbin 40701
1964, Ohio State U

In-Training

Jefferson

Richard W. Bock, MD — S
Steven B. Burton, MD — P
Kenneth D. Calhoun, MD — FP
Timothy R. Killeen, MD — IM
Silas E. Lucas, III, MD — ORS
J. Anthony Shaheen, MD — S
Barbara T. Wojda, MD, — IM

Northern Kentucky

Geralynn Duell-Breidenstein, MD — FP

DEATHS

John J. Salter, MD
Weber City, VA
1913-1992

John J. Salter, MD, a retired pathologist, died February 14, 1992. Dr Salter graduated from St. Louis University School of Medicine in 1939 and was a life member of KMA.

John F. Ice, MD
Louisville
1927-1992

John F. Ice, MD, a psychiatrist, died July 9, 1992. Dr Ice graduated from George Washington University School of Medicine in 1953 and was an active member of KMA.

Louis R. Putnam, MD
Covington
1930-1992

Louis R. Putnam, MD, a pulmonary diseases physician, died December 30, 1992. Dr Putnam was a 1956 graduate of Columbia University College of Physicians and Surgeons and was an active member of KMA.

Roy E. Bingham, MD
Louisville
1901-1993

Roy E. Bingham, MD, a retired psychiatrist, died February 3, 1993. A 1932 graduate of the University of Louisville School of Medicine, Dr Bingham was a life member of KMA.

Robert G. Callaway, MD
Louisville
1927-1993

Robert G. Callaway, MD, a family physician, died February 3, 1993. Dr Callaway graduated from the University of Louisville School of Medicine in 1955 and was an active member of KMA.

Thomas E. Campbell, MD
Louisville
1929-1993

Thomas E. Campbell, MD, a retired ophthalmologist, died February 6, 1993. Dr Campbell was a 1958 graduate of the University of Louisville School of Medicine and an inactive member of KMA.

Jeffrey D. Johnson, DMD
Louisville
1956-1993

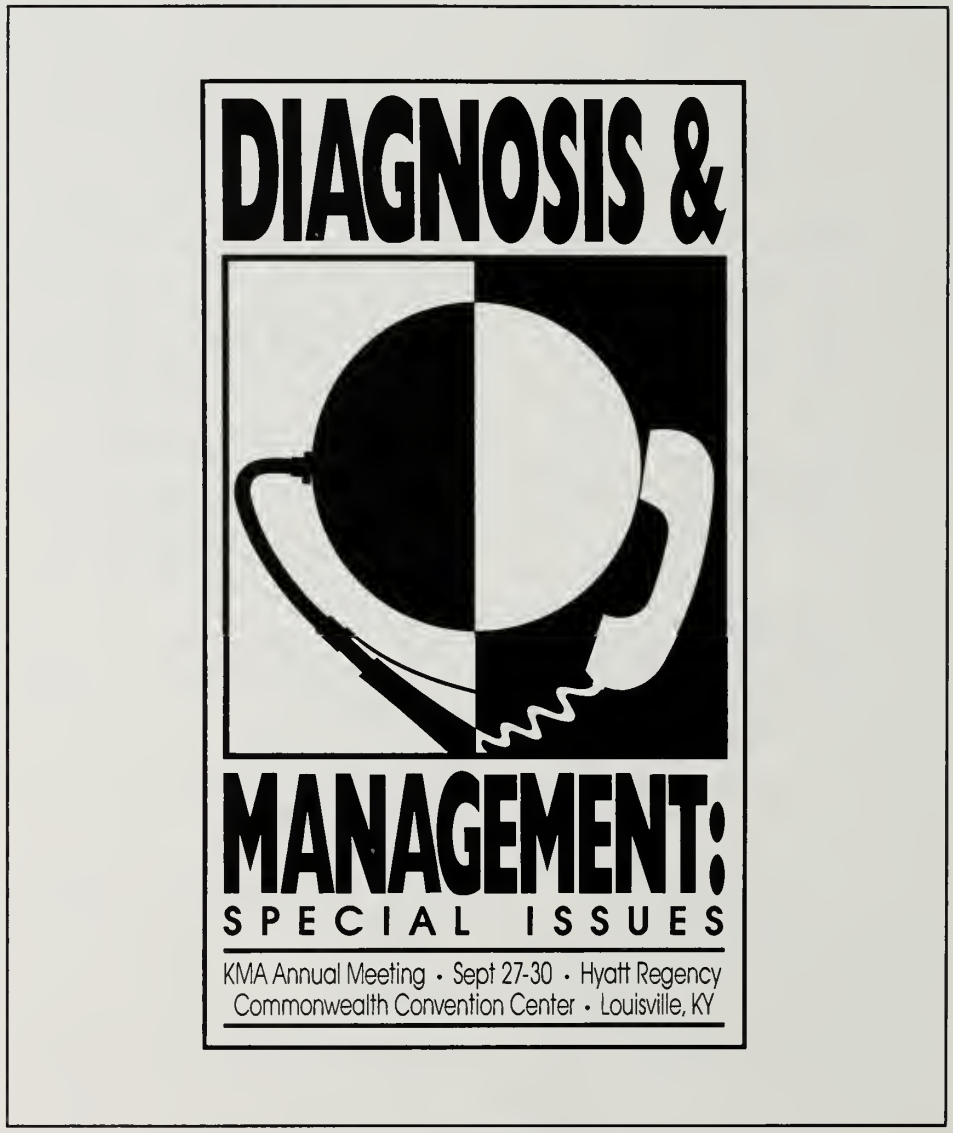
Jeffrey D. Johnson, DMD, a periodontist, died February 7, 1993. A 1983 graduate of the University of Kentucky School of Dentistry, Dr Johnson was an associate member of KMA.

Malcolm D. Thompson, MD
Louisville
1900-1993

Malcolm D. Thompson, MD, a retired surgeon, died February 8, 1993. Dr Thompson graduated from the University of Pennsylvania School of Medicine in 1922 and was a life member of KMA.

John T. Bate, MD
Louisville
1898-1993

John T. Bate, MD, a retired surgeon, died February 25, 1993. A 1922 graduate of the University of Virginia School of Medicine, Dr Bate was a life member of KMA.



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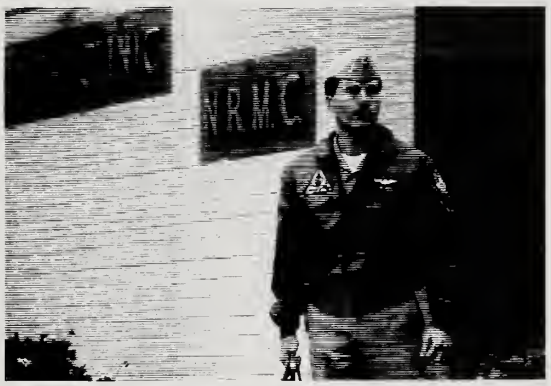
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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occesionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with aspirin, antacids [1 hour prior to PRAVACHOL (pravastatin sodium)], cimetidine, nicotinic acid, or probucol, no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Hardenan gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Leboretory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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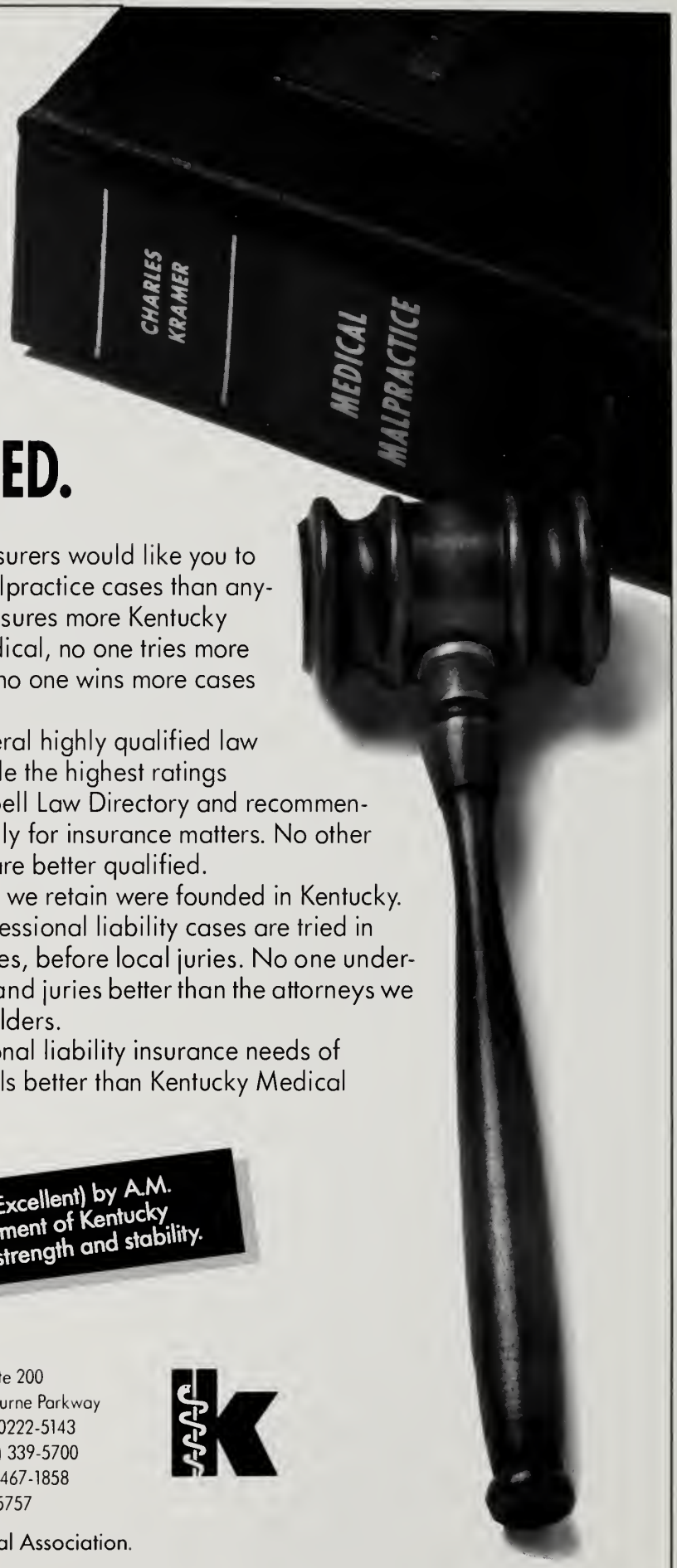
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William B. Monnig, MD

Testimony Before the Governor's Commission on Health Care Reform

"If you choose to ignore our efforts and expertise, it makes sense to at least listen to the wisdom of 500 experts that have been assembled at a national level to address these same issues. Our final thoughts are perhaps you should fix Medicaid and await the Clinton parameters."

The following testimony was presented before the Governor's Commission on Health Care Reform, at a meeting held in Frankfort, Kentucky, on April 13, 1993.

The Kentucky Medical Association is grateful for the opportunity to address you concerning health care reform. With me today are Russell Travis, a practicing neurosurgeon in Lexington, and Chairman of the Board of Trustees of the KMA; Ardis Hoven, a practicing internist who specializes in infectious diseases including AIDS, and President-Elect of the KMA; and Bill VonderHaar, a family physician in Louisville, and Secretary-Treasurer of KMA.

The Kentucky Medical Association is submitting separate written testimony supplementing our presentation on health care reform, along with our response to the Governor's proposal. The KMA represents 5,000 physicians, or approximately 80% of licensed practicing physicians in Kentucky. Kentucky physicians employ approximately 25,000 men and women and represent one of Kentucky's major industries.

The Kentucky Medical Association is dedicated to promoting the health of the people of this Commonwealth and being the patient advocate in the diagnosis and treatment of disease and injury.

We have been advocating health care reform in Kentucky for many years. We have placed the improvement of quality patient care above all else.

We are proponents of continuing to improve the quality of patient care. Despite the fact that we are one of the poorest states in this country, our medical care is second to none.

We are, and the public should be, concerned about an all powerful governmental agency assuming the responsibility for quality patient care. This will occur in an environment where decisions will be driven by a legislative process mired in the dilemma of recurring budget deficits. The all-powerful authority will be created by legislative fiat and cannot

be guided by practicing physician members. In our opinion, this is a proposal that warrants careful reevaluation.

We congratulate the Governor for proposing health care reform. The KMA has made every effort to present its position and submitted a plan to you in May 1992. In addition, we have worked with a coalition of providers and the Kentucky Chamber of Commerce to develop a plan. That information will probably be presented by Dr Higgins.

Many of the reforms proposed we enthusiastically endorse, including expansion of Medicaid; reforming insurance and the development of a basic health insurance coverage plan; development of a small employer health reinsurance program; requiring individual insurance coverage either through employer-provided coverage or some other mechanism with appropriate subsidies to small business; rural and primary care initiatives for primary care physician recruitment and education; school-based health education; consumer-based health education; and mandatory seat belt usage.

Attempting to solve the health cost and access problem is not a new exercise for KMA. In 1948, KMA founded the Rural Kentucky Medical Scholarship Fund. Since its inception, we have loaned almost $4 million to medical students and have placed over 300 physicians into 94 of the 120 counties of Kentucky. The Scholarship Program is still acclaimed nationally as the model for other scholarship programs.

The KMA developed a program for the indigent of Kentucky in 1985, and Dr Travis made presentations on three separate occasions to define the problem, propose a solution, and recommend funding. That program, as outlined in our written testimony, covered the eight basic medical services.

The Governor's plan relies heavily on primary care physicians to provide basic and preventive care. The program of managed care proposed may have to be phased in. There simply aren't enough primary care physicians to implement the proposal at this juncture. Of Kentucky's 5500+ actively *practicing* physicians, 43% are currently in the fields of family practice, internal medicine, pediatrics, and obstetrics and gynecology — falling under the category of primary care. Today, 45 Kentucky counties currently meet federal designation as a shortage area. Five years ago, only 36 counties fell within these guidelines. Our statistics show that one-fourth of all practicing primary care physicians are age 55 or older, and KMA hears from an increasing number of physicians requesting information on retirement and how to close their practices. On the other side of the spectrum, of the physicians licensed within the last 5 years and currently practicing in the state, only 42% are in a primary care specialty. We believe it important that physicians not perceive reform as punitive. If they do, many will choose to retire early or reduce their practice. While KMA supports the use of physician extenders, there is no evidence that physician assistants and nurse practitioners are any more likely to live and practice in critical shortage areas than physicians. Any legislation enacted should limit physician extenders to critical areas; permit no more than two per physician; and prohibit the prescription of scheduled drugs.

"We are, and the public should be, concerned about an all powerful governmental agency assuming the responsibility for quality patient care."

In 1984, citizen Brereton Jones came to the KMA Board of Trustees and asked us to work with him to develop a program to provide care to the uninsured. The KMA and Governor Jones founded the Kentucky Physicians Care program. This program has been in existence for 7 years, and 2,500 (or 50%) of practicing Kentucky physicians have made themselves available to the indigent of Kentucky via a 1-800 number. If a patient is uninsured and not qualified for Medicaid, they are referred to a participating physician. Over 52,000 patients have been treated through the Kentucky Physicians Care program, with an additional 20,000 certified for eligibility. An average KPC patient has four encounters, so that means that over 208,000 free physician visits have taken place. Since the program's inception, we have received approximately 118,000 calls. The Kentucky Physicians Care program was expanded to include all hospitals in Kentucky, 437 pharmacies, and four major drug companies, and is the cornerstone of the Kentucky Health Care Access Foundation. This is an excellent example of government, private enterprise, and providers getting together attempting to solve a problem.

It is imperative that we find a way to insure the 15% to 20% of uninsured Kentuckians. No reform plan can successfully address cost and access without addressing cost shifting for uninsured or underinsured patients. Taxing physicians, hospitals, pharmacies, and other providers and reducing fees and charges, yet failing to address the uninsured problem, has a potential for disastrous consequences. Despite the rhetoric, President Clinton and Congress realize there is not enough money in the present system to insure the hundreds of thousands of uninsured. This problem is compounded by the fact that the uninsured have gone without proper medical care and are generally

unhealthy. Once they obtain coverage, they will access the system and obtain the care they need and deserve.

The KMA supports the Governor's program to assure access. This has been his one goal for many years. We understand the plight of small businesses and their legitimate concerns. However, we find it unacceptable that national chains, franchises, and other successful businesses who make tremendous profits shift the cost of employees' health care to providers and the paying public.

"It is imperative that we find a way to insure the 15% to 20% of uninsured Kentuckians."

Physicians receive 19 cents of the health care dollar, with at least 50% of that dollar applied to overhead. The average physician employs four people. Accepting the fact that $894 billion are spent on health care, reducing reimbursement to physicians by 50% will still result in over $800 billion being spent on health care. We are more than willing to work to correct instances of overcharging, fraud, and other abuses of the patient's trust, but need FTC waivers that would allow us to more effectively police ourselves.

Medicaid reimbursement prior to 1978, and actually into the late 80s, was almost non-existent. In fact, surgeons were paid a maximum of $75 whether they removed a toenail or did brain surgery. However, Kentucky physicians took care of the Medicaid recipient then and will continue treating them. Physicians in Kentucky receive less than 12 cents of the Medicaid dollar. Prior to 1991, Medicaid reimbursement was still extremely low, and most physicians who treated Medicaid patients were not even reimbursed for overhead costs. The driving force in the growth of Medicaid costs can be attributed to expansion of recipients. We understand over 100,000 Kentuckians have been added to the Medicaid rolls in the past 2 years. Physicians are taxed at a rate of 15% of Medicaid reimbursement which, on a three-to-one match, raises $150 million for the state. However, physicians receive $75 million in return, with the remainder apparently going into the general fund.

Finally, it should be understood by the Commission that physicians' fees are already fixed. Over 90% of private patients are in programs with fixed physician reimbursement schedules set under their contract. That includes Medicaid, Medicare, Blue Shield, Humana, HMOs, PPOs, and other insured plans.

In any other discussion of health care reform, the first decision that must be made is to determine whether Kentuckians will accept a painful prescription to resolve health care access and costs.

Secondly, the Commission must have the will to make painful decisions that undertake the responsibility of rationing health care and accept liability for the provider when care must be denied or reduced. That's what other countries that critics of our system commonly compare us to have done. If you want to lower costs, that's what this state and this nation are going to have to do. **Physicians are trained to provide medical care, not to ration that care.**

There have been periodic discussions about hospitals closing, and that may be necessary. However, you need to make those decisions, and legislators should know that those communities not only will lose their hospitals, but lose their physicians and, consequently, forfeit a community's future economic growth. Possible businesses are highly unlikely to locate where relative high-tech hospital/medical care is unavailable. Physicians spend approximately 10 years in training and are unlikely to practice in an area where there is no hospital and where they become triage practitioners.

The framework of any health care reform must meld with President Clinton's federal program. It will be extremely difficult to reform our system in a vacuum when so many competing and outside forces do not fall under state jurisdiction. Consequently, the KMA believes that until the President releases his plan and Congress has had an opportunity to review it, it would be in the best interest of Kentucky to correct Medicaid and wait until the 1994 Session to address extensive reform.

"We will oppose any attempt to return the Board of Medical Licensure to the political arena."

We have four major concerns with reform proposals, which are outlined in our written testimony. We are concerned with a politicized Health Care Authority and its charge to control the entire health care sector without direct citizen and legislative input. However, any Authority should have a provider who is knowledgeable of the system. Government control of fees or charges has never worked, and practically every health economic expert has so stated. A plan based on managed competition utilizing a gatekeeper can preserve patient choice of providers, reduce costs, and maintain the free enterprise system. But the author of the managed competition concept, Alan Enthoven, has stated on many occasions that stringent rate review

has no place in a managed care plan. Bureaucratic costs will offset any savings resulting from a suffocating government-controlled system.

Prior to legal restrictions on our interventions, we were strong supporters of peer-to-peer disciplinary actions to maintain the quality and affordable cost of physician services. Because of judicial decisions and court interpretation of Federal Antitrust laws and regulations, the KMA was forced to withdraw from physician self-regulation.

We have maintained a strong commitment to quality and effectiveness of care through support of an independent Professional Licensing Board that was promoted by then-Governor Wendell Ford and was created by legislative action. That Licensing Board continues to serve the Commonwealth well.

We will oppose any attempt to return the Board of Medical Licensure to the political arena. Governor Wendell Ford removed the Licensure Board from politics in the early 70s, and the Kentucky Board of Medical Licensure is now recognized as one of the five most effective licensure boards in the US.

The third concern we have is, of course, the provider tax. We believe that indigent care is a societal responsibility and that a tax only on providers' gross revenue is extremely unfair. We are willing and prepared to pay our fair share, but favor funding mechanisms where all people participate in a fair and reasonable way.

We are concerned that members of the Commission are advocating reimbursement for services rendered be dependent upon adhering to practice guidelines that are authenticated by a nonphysician Authority. Such a suggestion further alarms us because the authors of such edicts obviously do not know that most disease processes have not been addressed by such guidelines, much less have the guidelines been professionally and scientifically validated. Those government representatives who would exclude physicians from having authority over the use of the guidelines are willing to place all Kentucky residents at risk for the sake of an experiment in the name of cost containment. There certainly is no evidence that immediate implementation of across-the-board guidelines is practical or good medical practice.

"We believe that indigent care is a societal responsibility and that a tax only on providers' gross revenue is extremely unfair. We are willing and prepared to pay our fair share, but favor funding mechanisms where all people participate in a fair and reasonable way."

The physicians of this state must have authority to determine what is good medical practice, and that ability should not be over-ridden by an Authority that has no practicing physician representation.

You legislators certainly are the experts on state government spending. No one realizes better than you the uncertainty of state revenues and spending.

If you believe that health care is a societal right, shouldn't there be an equitable method of financing it? We believe the federal government has no intention of continuing the federal matching program for Medicaid past 1995. If you succeed in limiting provider payment increases to the CPI, do nothing to curb their expenses, add to their administrative costs through requirements to supply data, and do nothing to diminish defensive medicine costs, how do you expect to make physician patient care attractive, especially in rural and inner city areas?

Before you choose to endorse a state-level initiative on health care reform, be aware of the pitfalls and take more seriously physician concerns. Your decisions may undermine a patient care system that, despite all of its drawbacks, gives excellent care to more than 85% of the people. If you want a reform system that works and saves money, invite us to the table — we will help you.

In fact that concern seems to be the driving force for health care reform. Health care is costing too much and is affecting the budget adversely. You are saddled with the responsibility of making the budget balance. If that is your main concern, why force more of the cost of health care into the state budget? Is it practical to mandate rate regulation for 1/7th of the whole economy? Are you aware of a single time where rate setting has been tried and was effective in controlling the costs of professional services?

We have already produced a health care plan that achieves affordable health care for all by the year 2000. It was a cooperative effort by people who spend their lives administering to the health care needs of the people of this state. It is a practical plan and a fair plan that involves both the government and private sector.

If you choose to ignore our efforts and expertise, it makes sense to at least listen to the wisdom of 500 experts that have been assembled at a national level to address these same issues. Our final thoughts are perhaps you should fix Medicaid and await the Clinton parameters.

William B. Monnig, MD
KMA President

American Medical Association
Physicians dedicated to the health of America

For Your Benefit

AMA renews call for physician input on health care reform

During the crucial first 100 days of the Clinton Administration, the American Medical Association stepped up its involvement in the health system reform debate. AMA's goal: to ensure that patients' needs remain the focus of system reform.

The AMA organized an unprecedented two-day Washington summit, "A Time for New Partnership," on March 23-25 to encourage dialog between physicians and the Clinton Administration and Congress. Physicians from across the country gathered in Washington to hear Vice President Al Gore speak on health system reform; HHS Secretary Donna Shalala and Majority Leader George J. Mitchell (D, Maine) also addressed the physicians.

After a briefing by AMA legislative staff, the physicians visited with their representatives in Congress.

The AMA is continually working to make the voice of American physicians heard in Washington. As AMA EVP James S. Todd, MD, stated in a letter to White House senior health policy adviser Ira Magaziner, "Bring us into the process, and we can help make it work. Without the 'buy-in' of people in the front lines of health care delivery, enactment and implementation of reform will be much more difficult."

Contest boosts AMA's anti-tobacco crusade

AMA and U.S. Surgeon General Antonia Novello, MD, are sponsoring a nationwide contest to increase children's awareness of the dangers of smoking. AMA President John L. Clowe, MD, said the contest is part of the AMA's and the surgeon general's continued campaign to achieve a smokefree environment by the year 2000.

The contest is designed to combat the tobacco industry's "spending millions of dollars in advertising to encourage young children to start smoking."

AMA and the surgeon general last year sponsored a protest march in Chicago against cigarette advertising that targets children. They also demanded that R.J. Reynolds Co. drop ads featuring the company's most effective marketing tool — the cigarette-smoking Old Joe Camel that appeals to children.

The nationwide contest, called "Say No, Old Joe," is aimed at the Camel cartoon. Studies published in the December 10, 1991 JAMA showed children six years of age and older found the character just as recognizable as the Disney Channel's Mickey Mouse logo. Old Joe Camel's appeal increased smoking of that brand among children from five percent to 32 percent during a three-year period, the studies found.

"The AMA will continue its fight to eliminate underage smoking and put pressure on cigarette manufacturers who use deplorable advertising tactics to entice children to begin smoking," said Lonnie R. Bristow, MD, AMA vice chair. "Maybe Old Joe Camel has taken his last puff?"

Prepared by the Department of Communications Services. For information, call 800 AMA-3211, ext. 4416.



Functional Voiding Disorders of Childhood

Anthony J. Casale, MD

Voiding problems in children are common and lead to symptoms of incontinence, urinary tract infections, urinary frequency, and urgency. Most voiding disorders occur in children with relatively normal neurologic and urinary systems and are believed to be functional in nature. Functional voiding disorders have a complex etiology involving faulty decision making and toilet habits. These disorders present with various combinations of symptoms and may be difficult for the physician and the parents to recognize. A catalog of the most common voiding disorders and their treatment is outlined. The close relationship between voiding and stooling dysfunction and their treatment is also presented.

Introduction

Voiding disorders in children are common, leading to many troublesome symptoms. The relationship between cause and symptom is confusing to the parents and often to the physician. Treatment of the symptoms alone, such as a urinary tract infection, often is only temporarily successful, leading to recurrent symptoms, which creates anxiety for both family and doctor. Understanding the underlying cause requires knowledge of the normal development of control of voiding in children, the normal function of the bladder appropriate for age, and the specific disorders that affect voiding, and how they, in turn, cause symptoms.

Functional disorders are, by definition, not entirely due to abnormal physiology, which in this case would involve either the nervous or urologic systems. While the urinary tract functions abnormally in these children, the most important factors in causing dysfunction involve poor decision making and patterns of behavior surrounding toilet habits. In order to understand, diagnose, and treat these problems, we must document the symptoms and the behavior which surrounds them. In some cases, we must change the child's behavior in order to cure the disorder, while in other cases the understanding of the disorder and its natural course alone may provide great relief for the child, family, and physician.

Symptoms

Voiding disorders lead to a number of specific symptoms (Table 1). Some may be isolated, such as frequency of urination or urinary tract infection, but most often symptoms occur in groups. The presence and severity of specific symptoms vary so that the dominant presenting symptom may be different in children with the same voiding disorder. Through careful questioning and record keeping the physician can uncover the full range of symptoms and in this way diagnose and treat the underlying voiding disorder.

Table 1. Symptoms of Functional Voiding Disorders of Children

- Changes in frequency
 - Increased
 - Decreased
- Urgency
- Daytime wetting after toilet training is completed
- Nocturnal enuresis
- Dysurea
- Urinary tract infection
 - Cystitis
 - Pyelonephritis
- Abdominal pain
- Perineal pain
- Constipation
- Encopresis

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The most common single symptom is frequency of urination. Children who are toilet trained usually void three to six times a day. Abnormal urinary frequency is a disruptive problem since it interferes with the other activities of the day, especially school and family trips. Urgency or the irrepressible desire to void usually accompanies increased frequency. Children abruptly become very uncomfortable and are unable to continue their current activity without stopping to void.

Daytime wetting is not normal after the age of toilet training and is particularly distressing to the school-age child because of peer pressure. Wetting comes in various forms with various causes so the pattern of wetting, including the amount and time of day that wetting occurs, is particularly important. Nocturnal enuresis as an isolated problem will not be discussed here since it has a different pathophysiology and treatment from other voiding disorders. Many of the children with voiding disorders will also wet at night, but all have daytime symptoms. Treatment is directed initially at daytime problems because they generally are more distressing for family and child.

Dysuria or painful voiding as a symptom may be related to infections or to dysfunction of the bladder. It can be persistent or occasional and its severity varies tremendously. Once the child begins to complain of pain, however, the family usually seeks medical attention, despite a long history of other less dramatic symptoms.

Urinary tract infection, a common presenting symptom, may occur as lower tract infection (cystitis) or upper tract infection (pyelonephritis). Usually these symptoms are recurrent and are often separated by long periods of time. Unlike other symptoms, infections pose a real threat to the child's health. Urinary tract infections, particularly pyelonephritis and infection related to vesicoureteral reflux, can lead to scarring and damaged kidneys. Documented urinary tract infection requires prompt evaluation, treatment, and follow-up.

Just as voiding too frequently is a symptom of bladder dysfunction, so is infrequent voiding. Holding of urine for long periods of time is often seen as a virtue by some parents because it allows an uninterrupted schedule of daily activities. It is clear that some children void twice a day and have no problems whatsoever. It is also evident that many children with this pattern develop symptoms of pain, wetting, and infection.

Lower abdominal pain and occasionally perineal pain may result from voiding problems. Usually these pains are the direct consequence of bladder spasms and can be quite severe. Sometimes the pain is relieved by voiding, but the child may learn to postpone voiding, and the painful spasm may pass, making the cause of the pain difficult to diagnose. Often these children have had prior evaluations of the gastrointestinal tract in attempts to discover the cause of their pain.

Functional voiding disorders occur in children who do not have significant underlying urinary or neurological conditions. One must rule out these other conditions when evaluating a child with bowel and/or bladder symptoms. The children must be monitored during treatment to make sure the diagnosis is correct. The failure of established treatments, the progression of old symptoms, or the appearance of new complaints all may bring the diagnosis of a functional disorder into question. Certain signs and symptoms are also a warning of other conditions and should lead to further evaluation and consultation.

Table 2. Symptoms Uncharacteristic of Functional Disorders

Severe pain on urination
Rectal pain
Penile or vaginal pain
Straining to urinate
Slow urinary stream
Back and leg pain or weakness

Some symptoms, although related to bowel and bladder activity, are uncommon in functional disorders and should alert the physician to consider other options (Table 2). Severe pain on urination, rectal pain, and penile or vaginal pain are unusual in most functional bladder problems unless infection is present. Consistent or severe pain should be considered a warning for further evaluation. Straining to urinate and a slow urinary stream are also not part of the usual group of functional bladder symptoms. Back and leg pain or weakness, either at the time of diagnosis or developing during treatment, require immediate attention because they may be associated with spinal cord dysfunction.

Normal Evolution of Bladder Control

The infant has a completely automatic bladder which functions reflexively under control of the lumbosacral spinal cord. There is little conscious sensation and no central nervous system involvement in bladder control. Voiding occurs approximately 20 times a day in small amounts.[1]

Within a few months, the infant develops discomfort with a full bladder and shows signs of having sensation during voiding. While he may also show relief after voiding, there is still no control, just awareness.

During the first 2 years of life, the capacity of the bladder increases, and the volume of voided urine increases fourfold, while the number of voids decrease 50%. Sensation continues to develop, but control lags behind on both a neurologic and intellectual basis.[1]

The first step in voluntary control involves the sphincter mechanism. This is the sleeve of both striated and smooth muscle that surrounds the bladder neck and the urethra and is responsible for providing varying resistance to the flow of urine leaving the bladder. The striated portion of the sphincter is under voluntary control, which requires adequate neurological development along with the learned skill for using it on demand. This accomplishment is rare under the age of 18 months; most children acquire control by age 3 years.[1]

The last developmental step in bladder function is control of the voiding reflex. This involves the modulation of the spinal cord reflex center by the central nervous system. This allows voluntary initiation and inhibition of bladder muscle (detrusor) contraction coordinated with appropriate contraction or relaxation of the sphincter. Most children master this by age 4. It is a difficult reflex to control, and voluntary initiation of voiding is still difficult for many adults.[2]

Normal Urinary Control

Once the child is completely toilet trained, bladder control is identical to that of the adult. Understanding normal bladder control requires a knowledge of the relationship between two major bladder muscle groups: the detrusor, which surrounds the body of the bladder as an interlocking layer of smooth muscle fibers, and the sphincter muscle, which is made up of smooth and striated muscle and surrounds the bladder neck and urethra. This system is controlled through the spinal cord. There is direct voluntary innervation of the sphincter by the brain, but only indirect control of the detrusor, as the brain must act through the voiding reflex center in the lumbosacral spinal cord. For this system to function appropriately, coordination or synergy between the two muscle groups is paramount. Incoordination or dyssynergy between the detrusor and sphincter muscles leads to problems in function and control.

Normally the bladder performs two apparently simple acts which are, in fact, very complex. They require little conscious effort once learned. The bladder stores urine, and when full, is emptied at an appropriate time and place. During bladder filling, the detrusor is completely relaxed, providing low-pressure urine storage. There is increased sensation and awareness as the bladder nears functional capacity, causing discomfort when full. As the bladder fills, the spinal cord reflex center provides appropriate input to the sphincter muscle. When bladder pressure increases as volume increases, the sphincter muscle becomes more active, preventing urine from leaking. Coughing or straining does not result in urine leakage because the reflex center compensates for the increased pressure in the bladder by increased sphincter muscle pressure.

During bladder emptying, the detrusor and the sphincter muscles reverse roles. To void efficiently, the detrusor must contract while the sphincter muscle must relax completely. This forces urine from the bladder at pressures higher than those during storage but low enough to prevent damage to the bladder. This coordination or synergy between muscle groups is most important during voiding.

Transitional Problems

In reviewing the development of bladder control from infant to adult, it is obvious that it is a gradual process, taking several years to develop fully. Often this is not a smooth process, with starts and stops and temporary setbacks along the way. All children have some of the problems and symptoms of bladder dysfunction outlined above at one time or another, but they are intermittent and do not persist. These are the transitional problems of toilet training and are to be noted by the physician and tolerated by the parents. Symptoms should be evaluated only if they worsen significantly or if they persist past the time toilet training should be completed. The only exception to this rule is the presence of infection, which deserves

Table 3. Functionol Voiding Disorders of Childhood

	Age (Years)	Gender	Symptoms	Frequency
Doytime urinory frequency	4.5	55% boys	Doytime frequency ond urgency	Common
Stress incontinence	9 to 15	Mostly girls	Normol or infrequent voiding. Incontinent in smoll omounts with octivity	Rore
Giggle incontinence	7 to 15	Mostly girls	Normol voiding pottern; incontinent in lorge omounts with loughing	Uncommon
Lozy Blodder Syndrome	7 to 15	Mostly girls	Very infrequent voiding; moy be incontinent; urinory infections; constipotion	Uncommon
Unstoble blodder of childhood	6 to 12	Mostly girls	Doy ond night incontinence; urgency ond frequency; urinory infections; posturing to prevent voiding; constipotion; encopresis	Common
Non-neurogenic neurogenic blodder	6 to 12	Mostly boys	Doy ond night incontinence; urinory infection; urgency; intermittent voiding; constipotion; encopresis	Uncommon

evaluation independent of the stage of toilet training.

Evaluation of Children with Voiding Dysfunction

Children with symptoms of voiding disorders need a comprehensive examination. The history should include number and frequency of urinary tract infections; urinary frequency and urgency; whether the child wets, and if so, when; bowel habits and problems; difficulty in toilet training; age when trained; duration of symptoms and any progression of them; any behavior surrounding trips to the toilet, such as holding the groin or squatting; and questions about coordination of the legs and toes and any pains in the legs or back.

The physical examination can be limited to the abdomen, back, perineum, and a basic neurologic examination, including leg reflexes and lower leg and foot strength. The appearance of the lower back is important: Is the spine straight? Are there hairy patches, pigmented areas, or cutaneous dimples or sinus tracts? Bony and cutaneous anomalies may herald the presence of malformations of the spinal canal and cord, which often affect bladder function. Does the rectal sphincter tone seem appropriate? This also may reflect spinal cord and nerve root function. Finally, any genital swelling or trauma may reflect the possibility of sexual abuse. The examining physician must evaluate all of these possibilities. The urine must be examined for infection and specific gravity. Urine culture should be performed when infection is suspected.

An ultrasound examination of the kidneys, looking for hydronephrosis, renal size, and scars from past infections, should be performed. A voiding cystourethrogram is the most helpful x-ray. It gives information about bladder size, shape, trabeculation, the ability to empty completely, and the presence or absence of vesicoureteral reflux.

Finally, the most important part of the inital evaluation is a detailed history compiled by the parents regarding the child's voiding pattern. It should include the time of each void and the amount voided, including all wetting, how much, and when it occurred. Any unusual behavior or pain surrounding trips to the toilet should be noted, as well as bowel movements. After this record and the x-rays are completed, the child, parents, and doctor review the findings openly and a plan of treatment is initiated.

Terminology of Functional Bladder Disorders

The categorization and terminology of bladder disorder is somewhat confusing (Table 3). Sometimes it is based on function and sometimes on etiology. Understanding the terminology is not as important as understanding the patterns of symptoms and their causes.

Daytime Urinary Frequency Syndrome

This common problem occurs in toilet-trained children with a mean age of 4.5 years.[3] There is a sudden onset of frequency and urgency in children who until then voided normally. Only daytime symptoms occur in 77% of these children, and when nocturnal enuresis is present, it is unrelated to and unaffected by daytime symptoms. Fifty-five percent of those affected are boys.[3] The affected children are continent. Voiding occurs up to 5 times per hour during daytime only; the voided volume is small except for the first void in the morning. Most cases (82%) present during cold weather months and the etiology is unknown.[3] Anticholinergics such as oxybutynin are the only reported therapy and are usually ineffective. Untreated, this increased frequency resolves spontaneously but may persist up to 16 months with a mean duration of 2.5 months.[3] During the period of symptoms, it causes considerable anxiety for the patient and his parents. The principal treatment is reassurance for child and family.

Stress Incontinence

Stress incontinence, while a common problem in adult women, is rare in children. Typically, a small amount of urine leaks from a full bladder when the child suffers increased abdominal pressure from coughing or exercise. It is imperative that the child has a urologic and neurologic examination, as well as a urinalysis, since stress incontinence may be the result of other more serious medical conditions. Once the diagnosis of functional stress incontinence has been confirmed, the treatment is a planned voiding schedule. The child should actively plan to empty the bladder on a regular basis and avoid having a full bladder during physical activities, which could lead to increased abdominal pressure. In general this condition is benign and self-limited.[3] The sphincter exercises used by adult women with this condition have not proven to be helpful for children. Stress incontinence is limited almost exclusively to girls.

Giggle Incontinence

Giggle incontinence, another rare functional voiding disorder, affects mostly girls. These children have normal bladder function until they begin to laugh hard, causing their bladders to empty spontaneously. Again, a urologic and neurologic examination and urinalysis are important in diagnosing this benign self-limited condition. These children are encouraged to void prior to being in situations where they are likely to begin giggling. Anticholinergics may also help. Mostly a problem of preadolescents, giggle incontinence resolves with age.[4]

Lazy Bladder Syndrome

Lazy Bladder Syndrome is a problem limited almost always to girls. As the name implies, these children seldom void and suffer from decreased bladder sensation.[5] They may be incontinent between voidings because the bladder is filled past capacity and overflows. Sufferers of this syndrome typically do not void in the morning on awakening, can wait 16 hours or more between trips to the toilet, and usually void twice in 24 hours. Occasionally they develop urinary retention problems due to an overstretched bladder. Infections develop because of stasis of bladder urine, and the bladder eventually loses the ability to empty completely. Cystograms reveal a large, smooth-walled bladder. Treatment relies on a preset schedule for voiding. In severe cases, clean intermittent catheterization is necessary. Prophylactic antibiotics are also helpful in preventing infection.

Unstable or Uninhibited Bladder of Childhood

This common problem is found mostly in girls, occurring after toilet training is completed. Most children present with a history of daytime wetting, while others present with suprapubic pain and severe urgency and frequency. These children often squat or cross their legs to put off the urge to void. Eventually most of these children develop recurrent infections and many will have vesicoureteral reflux. The pathophysiology of this condition involves uncontrolled spasms of the detrusor muscle. These spasms produce immediate wetting in most patients, but some can successfully prevent wetting by forcibly contracting a strong sphincter muscle. This practice leads to high bladder pressures, which can distort the bladder remarkably. Cystograms often reveal trabeculated, thick-walled bladders, with diverticula and reflux of urine. Inefficient voiding leads to residual urine and infection. Some cases resolve with age but many worsen. Symptoms may persist

for years. Treatment can be quite successful. It includes intense bladder retraining, with timed voiding schedules and ample use of anticholinergics. Antibiotic prophylaxis is also an important part of treatment.[3,5]

Non-Neurogenic Neurogenic Bladder

This very uncommon syndrome involves day and night wetting, bowel dysfunction, encopresis, and recurrent urinary tract infection. It is a chronic functional disorder that is thought to be acquired. Voiding cystograms reveal a trabeculated bladder, vesicoureteral reflux in 50% of the cases, and a large post-void residual urine. During voiding, the detrusor functions appropriately, but the striated urinary sphincter remains narrow, preventing the free flow of urine. This learned incoordination or dyssynergia of muscle groups leads to high bladder pressures and inefficient voiding. Therapy directed at teaching the child to relax the urinary sphincter during voiding involves intense bladder training, anticholinergics, counseling, and in some cases, biofeedback, hypnosis, and clean intermittent catheterization.[6,7]

Relationship Between Bowel and Bladder Function

Understanding the relationship between bowel and bladder control is vital because of the interdependence of these systems. Most children with functional voiding disorders will also have symptoms of bowel dysfunction, notably constipation and encopresis. The same sacral nerve roots innervate the external sphincter of both the urethra and the rectum, and in fact, the muscles themselves are in continuity. When the rectum is stretched, due to impacted stool, bladder sensation and control decreases. Children with chronic constipation have been demonstrated to have uninhibited bladder spasms. The pressure exerted by a full rectum may distort the bladder and urethra, impeding bladder function. Whether these conditions are mediated by the nervous system or by physical forces of the rectum on the bladder, it is clear that there is a causal relationship between them. Bladder function often improves dramatically with better bowel function. Bladder emptying becomes more efficient, and since most bacteria that produce urinary tract infections are derived from the stool, resolution of encopresis lessens the threat of bladder infection.[8-10]

When treating children with functional voiding and bowel disorders, it is important to treat the bowel first or concurrently with the bladder. Treatment of bowel dysfunction includes dietary counseling, stool softeners, scheduling bowel movements, and laxatives. While the chronic use of laxatives should be avoided, they are helpful in the initial stages of bowel training. While many healthy individuals have bowel movements every 2 or 3 days, when retraining these children it is best to encourage them to have a daily stool following the evening meal. This allows the child an opportunity to master this task when he is usually more relaxed and his time is usually unscheduled. Bowel training is usually a long-term process that may be quite frustrating for child and parent.

Chronic Recurrent Problems

Recognition of the disorder by the physician and the patient's family is a difficult part of helping children with functional voiding problems. The doctor must be aware of the various behavior patterns that differentiate chronic bowel and bladder disorders from acute illnesses. Recurrent urinary tract infections, perineal rashes caused by incontinence, stained underpants (stool or urine), lower abdominal or perineal pain, and school and behavioral problems often are caused by functional voiding disorders. Often weeks or months of apparent good health may separate the appearance of these symptoms, but the key is the recurrence of similar complaints. Once the pattern is recognized, the underlying cause can be treated instead of dealing with the individual symptoms as they recur.

One of the most difficult tasks for the physician is to educate the parents so they understand the relationship between toilet habits and symptoms. On initial questioning, most patients know little of their child's toilet habits. The first step in the diagnostic process is to have the parents compile a detailed record of voiding and stooling patterns and associated behavior for their child. This focuses the parents on behavior that affects bowel and bladder function. The specifics of their child's frequency and amount of voiding and behavior — such as squatting, holding the genitals, running to the toilet, crossing legs, or bending at the waist to prevent voiding — often surprises the parents when a written record is compiled. It is the physician's duty to explain the relationship between behavior and the child's symptoms. Afterwards, all involved can work to correct the underlying cause.

Summary

Voiding disorders are common in children. Most are functional in that they are not due to significant neurologic or urologic pathology. Toilet habits, behavior, and decision making by children play an important part in the etiology of these problems. Voiding disorders lead to chronic and recurrent symptoms that may resolve spontaneously with age, but which often require treatment. Recognition by the physician of the symptoms and patterns requires careful questioning and record keeping. At diagnosis and during treatment, the physician must continually consider the possibility of neurologic or urologic disease and test to rule them out.

The first step in treatment is to define the disorder for the child and the parent and to convince the parents that toilet habits and behavior are related to their child's symptoms. Treatment involves the use of anticholinergics to lessen urinary urgency and bladder spasms, making bladder control easier. Often antibiotics are used nightly in low doses to prevent urinary tract infections. Finally, the child is retrained to void four times a day by scheduling trips to the toilet after meals and at bedtime. Positive reinforcement is used and it is hoped that the child will retain this voiding schedule when the period of treatment and retraining is over.

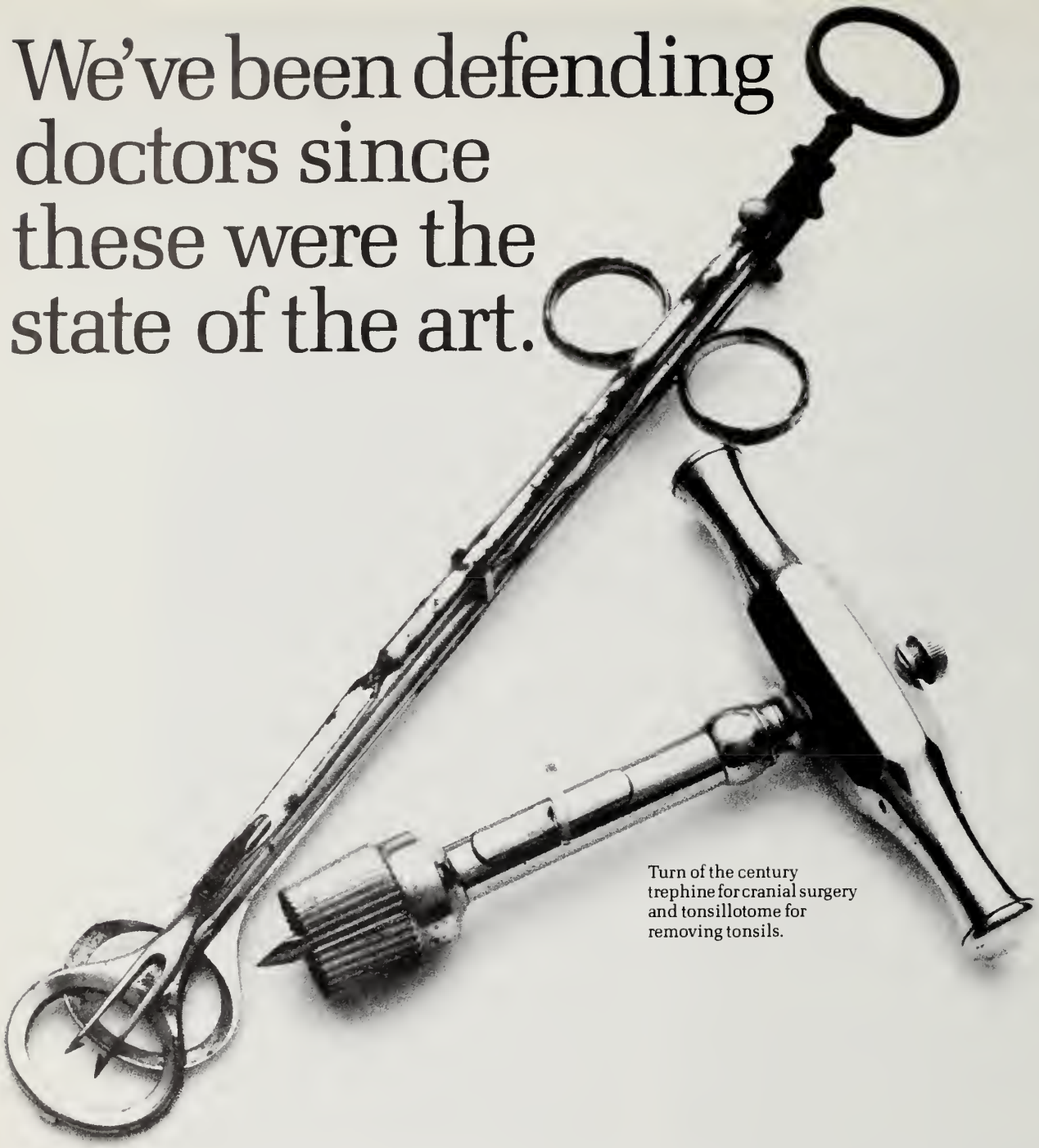
Bowel control problems are closely tied to, and often are a cause of, bladder dysfunction. Bowel problems must be treated concurrently with the bladder to achieve success. Stool softeners, diet, and occasionally laxatives are used to achieve a daily scheduled bowel movement after the evening meal.

Functional bladder and bowel dysfunctions are a frustrating problem for child, family, and doctor. The symptoms may be intermittent but can be very confusing and embarrassing to the child. Everyone wants a quick answer and cure, but there is none. The treatment takes time and effort on the part of the family and the child, and may take months to be effective. On the other hand, with honest effort, the results of treatment are surprisingly consistent and good. Many of these disorders may be preventable. Any medical pesonnel involved in the primary care of children should encourage parents to teach good toilet habits to their child initially and to pay attention to how their toddler goes to the bathroom.

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Metastatic Gastric Cancer Presenting as a Pelvic Mass

Paul D. DePriest, MD; Larry E. Puls, MD;
Richard W. Schwartz, MD; John R. van Nagell, Jr, MD

Traditionally, the gynecologist is the primary physician involved in the assessment of an adnexal mass. History, physical examination, and radiologic evaluation often fail to reveal extrapelvic etiologies for an adnexal mass, especially in the premenopausal woman. Recently three premenopausal women with a pelvic mass referred to the gynecologic oncology service at the University of Kentucky were each found to have gastric carcinoma metastatic to the ovary. This paper discusses the clinical presentation of these women and the indications for the evaluation of the upper gastrointestinal tract in a patient with an adnexal mass.

Introduction

Ovarian carcinoma will account for approximately 22,000 new cases in 1993 and 13,300 cancer deaths. The majority of these cancers are epithelial in origin. However, there is a subgroup of patients that presents with an ovarian mass that is actually metastatic disease. Of these lesions, which make up 10% of presenting carcinomas of the ovary, a certain number originate from the gastric mucosa. In the paper, we will present our experience with three such individuals.

Case Reports

Case #1
A 30-year-old white female, gravida 3 para 3, presented with a 2-month history of constant nonradiating lower abdominal pain and a 25-pound weight loss. Physical examination was unremarkable except for a fixed left adnexal mass approximately 6 cms in diameter.

Radiologic evaluation including computerized tomography (CT) scan of the abdomen/pelvis and barium enema showed a cystic left adnexal mass and ascites. A serum CA-125 level was 300 μ/ml.

Exploratory laparotomy revealed abdominal carcinomatosis and a 5 × 5 cm mass in the greater curvature of the stomach. A frozen section biopsy of this mass was consistent with gastric carcinoma. Surgery included a subtotal gastrectomy, gastrojejunostomy and omentectomy. Postoperatively, the patient recovered satisfactorily and was treated with platinum-based chemotherapy. She responded initially to chemotherapy but died of disease 6 months after diagnosis.

Case #2
A 47-year-old white female, gravida 2 para 2, presented with a 2-month history of abdominal distention, pain, and a 13-pound weight loss. Physical examination revealed an immobile 8 cm cystic right ovary and probable ascites. A CT scan confirmed the physical findings and showed gastric wall thickening. An upper GI endoscopy failed to identify any gastric mucosal lesions, and all gastric biopsies were negative for carcinoma. The patient's serum CA-125 level was 178 μ/ml.

Exploratory laparotomy demonstrated a primary gastric carcinoma with metastases to the omentum, colon, and right ovary. Due to the extent of tumor spread, effective surgical debunking could not be performed and postoperatively the patient received chemotherapy. She died of metastatic gastric cancer 11 months after surgery.

Case #3
A 31-year-old white female, gravida 3 para 3, presented to her internist with a 3-month history of dyspepsia and occasional vomiting. An upper GI series was unremarkable. Physical examination was significant for a 12 cm mobile pelvic mass. A CT scan demonstrated ascites and a 10 cm solid ovarian mass. The patient's serum CA-125 was 90 μ/ml. Abdominal carcinomatosis involving most of the peritoneal surfaces was noted at the time of surgery. Frozen section analysis of the left ovarian tumor revealed a signet-ring cell adenocarci-

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noma. The entire stomach was replaced with tumor, resulting in partial gastric outlet obstruction. The patient underwent a total gastrectomy with a Roux-en-y esophagojejunostomy. Despite chemotherapy, the patient died 3 months after surgery.

Discussion

Originally, a Krukenberg tumor was defined as a primary mucin-producing fibrosarcoma of the ovary.[1] At present, Krukenberg tumors are defined as metastatic ovarian tumors arising from the stomach, colon, appendix, or breast. The mean age of patients with this tumor is 45 years, and 40% of patients are under the age of 40.[2]

The clinician should always consider the possibility of a secondary ovarian neoplasm in a patient with a pelvic mass. Any woman with upper gastrointestinal tract symptomatology, weight loss, and an adnexal mass may benefit from both preoperative radiologic and endoscopic evaluation of the stomach as well as serum tumor marker determinations. Unfortunately, preoperative radiographic diagnosis of a Krukenberg of the ovary is difficult. Krukenberg tumors of the ovary are bilateral in 75% to 90% of cases,[2,3] but there are no distinguishing CT or ultrasound findings to differentiate this tumor from a primary ovarian malignancy. An elevated serum CA-125, while not diagnostic of ovarian cancer, should increase the suspicion of primary or secondary ovarian involvement.

Preoperative histologic diagnosis of gastric carcinoma in a woman with a pelvic mass usually indicates tumor metastases to the ovary. In these women, open laparoscopy may be helpful in determining the extent of disease and avoiding laparotomy. However, data on the utilization of laparoscopy in this setting is lacking. Debulking surgery, as performed in primary epithelial ovarian carcinoma, is not always beneficial in these patients. As reported by Petru et al, in a series of 22 primary gastric carcinomas presenting as ovarian cancer, the 5-year survival was 0%.[3] Therapy ranged from unilateral salpingo-oophorectomy to total debulking, with no variation in outcome. Seventy percent were dead at 1 year. In our experience, patients with metastatic gastric cancer have a dismal prognosis and usually die 6-12 months after detection despite appropriate chemotherapy.

Discovery at surgery of bilateral ovarian tumors should prompt the surgeon to obtain an intraoperative pathologic diagnosis. The diagnosis of a Krukenberg tumor necessitates a thorough assessment of the patient to ascertain the site of primary malignancy before proceeding with tumor debulking. Colon, breast, and stomach carcinomas occur in similar proportions as metastatic origins of ovarian carcinomas. Appropriate surgery may include resection of the primary lesion as well as total abdominal hysterectomy, bilateral salpingo-oophorectomy, and debulking versus biopsy only, and appropriate chemotherapy. Combination chemotherapy with FAM (5-fluorouracil, Adriamycin, mitomycin-c) or EAP (etoposide, Adriamycin, platinum) is indicated, particularly in patients with adequate tumor debulking.

There are no characteristic gross features of secondary tumors of the ovary, except the majority are bilateral.

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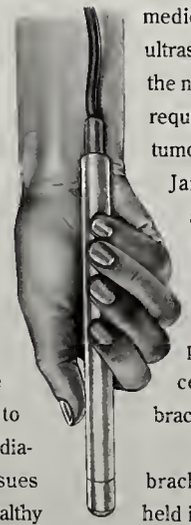
INTRAOPERATIVE RADIATION THERAPY

IORT, performed during surgery, utilizes targeted radiation to reduce or eliminate tumors without penetrating overlying tissue or damaging noncancerous cells surrounding the tumor. At The James, IORT is administered in a specialized operating suite equipped with a linear accelerator capable of emitting six million to 18 million electron volts. During treatment, a circular cone is positioned on the tumor and laser beams are used to align the accelerator before the prescribed high dose of radiation is applied. A minimum of 70 patients annually will be treated in the IORT suite.



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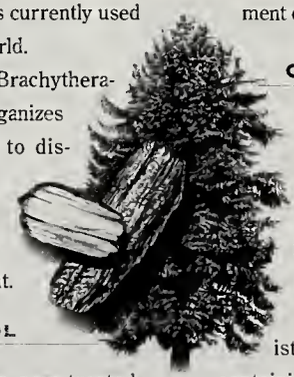


The James, one of the leading proponents of brachytherapy, actively applies several forms of brachytherapy for various cancers and is one of the few centers to implant young children.

Early methods of brachytherapy often required surgery and lengthy hospitalization and exposed patients' families and nursing staff to radiation. Researchers at The James are spearheading efforts on several fronts to overcome these problems. High dose rate brachytherapy allows the treatments to be given in a few minutes on an outpatient basis while totally eliminating radiation exposure to the medical staff. Fluoroscopy and ultrasound can be used to guide the needles into tumors without requiring surgery to expose the tumor. The researchers at The James have combined the advantages of IORT and brachytherapy to deliver intraoperative high dose rate remote brachytherapy to tumors normally inaccessible to either IORT or brachytherapy.

Radioimmunoguided brachytherapy utilizes a hand held instrument that can detect the radioactive material remaining in small tumors yet not visible to the surgeon. A critical innovation in cancer treatment, the instrument was developed at OSU and is currently used throughout the world.

The Section of Brachytherapy at The James organizes annual symposia to disseminate the latest information on this emerging oncology treatment.



TAXOL

The James has now treated patients from eleven states with taxol under a special National Cancer Institute Compassionate Use Program for patients with advanced ovarian cancer. In all, more than 54 patients have been treated at The James, the site of Ohio's only NCI-designated Comprehensive Cancer Center. This experimental treatment uses the scarce anti-cancer drug taxol, currently derived from the bark of the Pacific Yew tree. The taxol program at The James is designed only for women who have previously failed other treatment regimens and who have progressive disease. Other protocols using taxol in first line treatment are also available.

The Comprehensive Cancer Center is currently one of three centers in the United States using taxol in the treatment of breast cancer, and one of only two centers using taxol in the treatment of head and neck cancer.

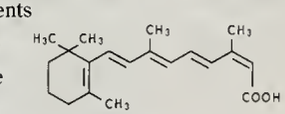
BORON NEUTRON CAPTURE THERAPY

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Clinical Theophylline Toxicity: Acute and Chronic

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Reliable methods for measuring serum theophylline levels have provided the clinician with a range of serum theophylline concentrations to maximize therapeutic results while minimizing potential adverse effects. Although serum theophylline levels are often quoted for diagnosing theophylline toxicity, intolerance of this agent is closely associated with clinical features that are more important than an absolute serum value. This report contrasts the two most common settings of theophylline toxicity and presents an approach to the treatment of each type.

Many organ systems respond to theophylline's competitive blockade of the adenosine receptor at the cellular level. In serum concentrations between 10-20 mg/L, the observed changes are commonly helpful in clinical medicine. Therapeutic pulmonary changes include relaxation of smooth muscle and enhanced central respiratory drive from an increased stimulation of medullary receptors.[1]

As serum theophylline levels increase, the agent begins to promote tissue accumulation of cyclic adenosine monophosphate (cAMP) by inhibiting the enzymatic effects of phosphodiesterase. As this occurs, the unwanted effects of theophylline begin to emerge. In addition to exaggeration of smooth muscle relaxation, an excess secretion of catecholamines causes dysfunction of the gastrointestinal, central nervous, and cardiovascular systems.[2]

Although the availability of reliable serum assays for theophylline has demonstrated a dose dependent relationship for adverse reactions in animals, humans show an unpredictable spectrum of theophylline kinetics and a variable range of tolerance. The quoted therapeutic range of theophylline concentration of 10-20 mg/L is arbitrary and patients may experience untoward side effects within this window or may have substantial toxicity when serum concentrations only slightly exceed the upper value.

Clinically, it is important to understand the distinction between acute intentional overdose and chronic inadvertent overmedication in order to afford the proper treatment and decrease morbidity and mortality.

Case Report

A 23-year-old female was admitted following the ingestion of 4.5 gm of sustained release anhydrous theophylline tablets and an undetermined quantity of ethanol in a suicide attempt. On initial evaluation, she was alert and oriented but extremely agitated and hostile. She was nauseated and had recurrent dark brown emesis. No hematemesis was noted. The patient was a chronic ethanol user and smoked two packs of cigarettes per day.

The patient's blood pressure was 80/40 mm Hg with a heart rate of 130-150 BPM. Her respiratory rate was 28 BPM. An oral temperature was recorded as 98.2°F. Her physical examination was unremarkable except for tachypnea, tachycardia, and diminished bowel sounds. Neurologically she was agitated but had no focal deficits.

Her biochemical profile measured the serum sodium as 143 mEq/L, potassium 2.7 mEq/L, chloride 107 mEq/L, bicarbonate 15 mEq/L, glucose 221 gm/dl, BUN 7, and creatinine 1.2. Her hemoglobin was 13.4 gms with a total of 26,400 white blood cells/mm3. A room air arterial blood gas measured the pH at 7.32, a $PaCO_2$ of 24 mm Hg and, a PaO_2 of 119 mm Hg. Serum toxicology documented the presence of caffeine, theophylline and ethanol. The theophylline level was 113 mcg/ml. The ethanol level was 0.01 gm/dl. An EKG showed sinus tachycardia at 139 BPM. Chest x-ray was normal. The patient was admitted to the

Table 1. Factors that decrease theophylline kinetics by affecting the hepatic P450 enzyme system.

Hepatic dysfunction — any cause
Congestive heart failure
Pneumonia
Fever
Acute viral infection
Cimetidine
Ranitidine
Quinolones
Erythromycin
Troleandomycin
Isoniazid
Propranolol
Disulfiram
Oral contraceptives
Caffeine
Age greater than 65 years
Obesity
Flu vaccination

Table 2. Factors that increase theophylline metabolism.

Infancy/adolescence
Cigarette smoking
Marijuana smoking
High protein — low carbohydrate diet
Carbamazepine
Phenytoin
Phenobarbital
Rifampin
Oral albuterol
Furosemide

intensive care unit and successful treatment of acute theophylline toxicity was undertaken.

Discussion

Theophylline toxicity commonly occurs in two distinct clincial settings.[3] Acute overdose results from intentional or inadvertent ingestions. Chronic overmedication accounts for 70% to 90% of the theophylline toxicities and most commonly results from patient or physician error and altered metabolism of theophylline.[4,5]

Sixty-six percent and 90% of patients with serum theophylline concentrations greater than 20 mg/L and 30 mg/L respectively, have clinical symptomatology.[4] The most common manifestations involve the gastrointestinal, central nervous, and cardiovascular systems. Seventy-two percent of patients develop at least one gastrointestinal symptom.[4,6] Nausea and vomiting are the most common, particularly in acute overdose. Other gastrointestinal manifestations include diarrhea, hematemesis, abdominal pain and anorexia.[4,6,7]

Central nervous symptomatology occurs in 45% of all patients with theophylline toxicity.[4] These adverse effects include seizures, hyperreflexia, tremors, anxiety, irritability, insomnia, headaches, nervousness, and hallucinations.[4-8] A small number of patients may become lethargic and confused.

Seizures are uncommon but potentially very serious. They are believed to be due to cerebral vasoconstriction mediated by theophylline induced hyperventilation and an increased concentration of cerebral cAMP.[7] Seizures attributable to theophylline toxicity represent a poor prognostic sign. Mortality from acute overdose with seizures ranges from 22% to 100%. The serum theophylline concentration threshold for seizures is higher in acute overdose.[3,4] Most of these patients (93%) have other signs of toxicity before the onset of seizures. In contrast, 60% of chronic overmedication patients have a seizure as the initial sign of toxicity. Patients with chronic overmedication and seizures have a reported mortality of approximately 20%.[4,5]

Theophylline has a positive chronotropic effect on the heart. Sinus tachycardia is the most common arrhythmia, but multifocal atrial tachycardia, atrial fibrillation, and atrial flutter also occur (15%).[4] Hypotension occurs more commonly in acute overdose and results from theophylline induced vasodilation. Hypotension may be exacerbated by hypovolemia because of emesis or diarrhea.[4,5] Ventricular tachycardia, ventricular fibrillation, and cardiac arrest are rare but have been reported in the acute overdose when serum theophylline levels exceeded 100 mg/L.[3,4] These arrhythmias occasionally occur in chronic overmedication of elderly patients with underlying heart disease.[9]

Metabolic derangements are present in 8% of patients with theophylline toxicity.[6] Catecholamine excess is associated with gluconeogenesis and hyperglycemia and an intracellular influx of potassium that may result in hypokalemia.Thus hypokalemia may serve as an early clinical predictor of serious theophylline intoxication.[7] Other metabolic disorders reported are hypercalcemia, hypophosphatemia, lactic acidosis[3,10,11] and elevated creatinine phosphokinase levels.[6]

In evaluating a patient with suspected the-

ophylline toxicity, the history should include the time of ingestion, dose, and type of theophylline preparation. This allows distinction between an acute excessive ingestion or chronic overmedication. Special attention should be paid to co-morbid disease and medications that may alter theophylline pharmacokinetics. A thorough physical exam should be performed with special consideration to the cardiac and neurologic systems.

Theophylline toxicity is graded from mild to severe. Mild toxicity is characterized by nausea, a heart rate less than 120 BPM, a systolic blood pressure greater than 120 mm Hg, and a lack of arrhythmias. Patients with moderate toxicity have emesis that responds to treatment and does not limit the use of oral activated charcoal, heart rate less than 140 BPM, systolic blood pressure greater than 100 mm Hg, frequent premature atrial contractions and premature ventricular contractions, agitation, and hyperreflexia. Severe toxicity is demonstrated by uncontrollable emesis that limits conservative treatment with oral activated charcoal, a heart rate greater than 140 BPM, a systolic blood pressure less than 100 mm Hg, significant supraventricular tachycardia or ventricular tachycardia, and seizures. If clinical signs overlap, the more serious category is assumed.

Most patients present with mild toxicity and recover completely. The clinical outcome in overdose correlates well with serum levels only in patients with acute theophylline toxicity. Mortality due to an acute excessive ingestion varies from 11% to 21%.[4] Patients with theophylline levels less than 100 mg/L generally recover without sequelae.[4, 5, 7] Serum theophylline levels correlate poorly with mortality in patients with chronic overmedication. Mortality can occur with peak levels between 40-60 mg/L,[4, 12] and 4% to 10% of patients with chronic overmedication die.[4, 5, 7] Signs of major toxicity may manifest without prodromal symptoms.[4, 5, 13] Older patients and co-morbid diseases increase the severity of toxic effects and mortality.[5]

The acute overdose patient should be monitored in an ICU if the theophylline serum level continues to rise despite treatment, if the serum theophylline level is greater than 60 mg/L, or if severe cardiovascular symptoms or seizures are evident.[5] Theophylline concentrations should be monitored every 2 hours until levels decrease on two consecutive measurements. The stomach contents should be evacuated to remove residual pill fragments via a large-bore nasogastric or orogastric tube.[14] Emesis should not be induced.

Patients with chronic overmedication whose theophylline level is less than 25 mg/L and who do not have a history of seizures or arrhythmias usually have a low incidence of life threatening complications. Other than discontinuing the medication, these patients do not need further intervention and do not require hospitalization.[8] Cardiac monitoring is indicated at serum theophylline levels between 25-60 mg/L. Admission to an ICU is indicated for serum concentrations greater than 60 mg/L or if the patient has underlying heart or central nervous system disease.[5, 14]

Oral activated charcoal is the mainstay of treatment in all but the most severely toxic patients. Oral activated charcoal effectively binds theophylline in the gastrointestinal tract. It is effective in eliminating theophylline from the bloodstream by gastrointestinal dialysis.[14] The recommended dose is 30-40 gm every 2-4 hours or 10 gm every hour. It may also be administered as a continuous drip that may be better tolerated in nauseated patients. This treatment should be continued until the serum level of theophylline drops below 25 mg/L.[7, 14] Sorbitol may be used adjunctly as a cathartic.

Charcoal hemoperfusion is the treatment of choice in life-threatening theophylline toxicity. This technique increases theophylline clearance five fold.[15] The indications for charcoal hemoperfusion in acute overdose include: a serum theophylline level greater than 150 mg/L or a serum concentration greater than 100 mg/L with moderate or severe symptomatology.

The role of charcoal hemoperfusion in chronic overmedication is less clear. It is, however, used in this setting when serum theophylline is greater than 60 mg/L and moderate or severe clinical toxicity exists; when theophylline levels are greater than 40 mg/L with moderate or severe clinical toxicity in patients with co-morbid cardiac, respiratory, or hepatic diseases; and when oral charcoal therapy fails.[7] Charcoal hemoperfusion has the disadvantages of being invasive and requiring specialized personnel and equipment. It may also cause thrombocytopenia, hemolysis and electrolyte abnormalities.[7, 14] Hypotension may limit the use of hemoperfusion.

Hemodialysis increases the clearance of theophylline by 50% but is less effective than charcoal hemoperfusion. Peritoneal dialysis has not proven as effective as hemodialysis or charcoal hemoperfusion.[7, 16]

Exchange plasmapheresis has recently been

shown as an effective means to remove both free and protein-bound theophylline. In a case report there was no significant difference in the elimination rate between charcoal hemoperfusion and veno-venous plasmapheresis.[17] Although larger controlled studies are necessary, arterio-venous or veno-venous plasmapheresis may prove to be a safe and effective alternative to charcoal hemoperfusion in patients with severe poisoning.

Emesis is difficult to control until serum theophylline concentrations reach nontoxic levels. Metoclopramide (Reglan) in large doses (20-50 mg IV) may be useful. An appropriate therapeutic goal is toleration of the majority of oral activated charcoal treatments.[7] It is important to recognize that prochlorperazine (Compazine) lowers seizure thresholds and is therefore contraindicated.

Diazepam, given intravenously, controls the majority of seizures.[5] Phenytoin as a single agent, however, is not effective and the addition of phenobarbital is generally necessary.[5,7] The use of thiopental infusion, paralyzing agents, and general anesthesia may be required in patients with status epilepticus who are unresponsive to more conservative therapy.[5,7,18] Prophylactic treatment with phenobarbital should be considered in patients with underlying neurologic disorders, very high serum theophylline levels, or both.[14]

Systemic hypotension is more common in acute overdose than chronic overmedication.[4] Hypotension is due to excess sympathetic activity and accumulation of cyclic AMP within the vascular smooth muscle.[7] Dehydration from vomiting and cardiac arrhythmias may exacerbate hypotension. Volume expansion is the treatment of choice. Sympathomimetics (dopamine, dobutamine, norepinephrine) are generally not very effective and may add to the patient's theophylline induced sympathetic stimulation.[7]

Beta-blocking agents have been effective in reversing hypotension due to theophylline toxicity. Their effect is not only mediated by decreasing rapid supraventricular tachycardia but by increase in peripheral vascular resistance. However, beta-blockers may provoke acute bronchospasm in patients with obstructive lung disease and may accentuate preexisting hypotension.[19] For these reasons, esmolol has the theoretical advantage by being semiselective and rapidly cleared once the infusion is stopped.

Cardiac arrhythmias occur infrequently but can be difficult to control. Rapid supraventricular tachycardia has been treated with beta-blocking agents and calcium channel antagonists with varying success.[7,19] Multifocal atrial tachycardia may respond to calcium antagonists.[20] Lidocaine and phenytoin have been used to manage significant ventricular arrhythmias.[18]

Hypokalemia due to an intracellular shift of potassium can be severe. Recommendations in the literature vary from aggressive potassium replacement to no treatment. There is no correlation between potassium levels and premature ventricular contractions in theophylline toxicity.[9]

The true prevalence of theophylline toxicity is undetermined, but is most certainly underreported. In a VA emergency department, serum theophylline concentrations were found to exceed therapeutic range in 10% of patients tested randomly.[4] This observation corresponds with the clinical experience at our teaching institution. We hope that this discussion will increase the index of suspicion for the adverse effects of this commonly used bronchodilator.

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Learning in the Real World

". . . I do feel the need for our profession to change the way we teach our future physicians."

While attending on rounds with several medical students and residents recently, a bright young medical student began a presentation of his newly admitted patient. This 55-year-old gentleman had come to the emergency room complaining of fever to 103°F, a single shaking chill, right-sided chest pain which was worse with inspiration, and a cough which was productive of yellowish-brown sputum. The student had meticulously performed a Gram stain of the sputum which demonstrated sheets of white blood cells and numerous gram-positive diplococci. A chest x-ray confirmed a right lower lobe pneumonia. The patient was a non-smoker, a non-drinker, and was otherwise healthy. The student pronounced the patient as having community-acquired pneumonia and stated that the patient had been treated with a third-generation cephalosporin and erythromycin.

I asked the student at that juncture to explain his choice of therapy. He then articulately enumerated the multiple potential microbiological causes for community-acquired pneumonia and suggested that the proposed regimen would "cover" all the possibilities. When asked what he felt was most likely the etiology of the patient's presentation, he quickly responded with "pneumococcal pneumonia" and suggested that erythromycin would possibly be adequate as the patient was penicillin allergic.

This encounter made me wonder why a fine student who had obviously learned the data on pneumonia, executed an effective history and physical, appropriately utilized a directed laboratory investigation, and reached a correct presumptive diagnosis felt then compelled to implement a treatment plan which almost reduced his previous endeavors to insignificance. Was it simply youthful lack of confidence? I doubted this given his management decisions in other circumstances. Was it a fear that I would condemn any action other than that which seemed supremely aggressive? We had spent a fairly long time together, and I had not sensed this previously. Was it an already inculcated fear of litigation? I hoped not, but realized the potential for it, even at this stage of development. I believe it was most likely a by-product of a skewed patient selection, largely limited to chronically ill, indigent patients, or my failure to teach an appreciation of the natural history of illness as it occurs in different populations.

While I don't know all the answers to my questions, I do feel the need for our profession to change the way we teach our future physicians. Whatever the changes, and many have been proposed, they must include a shift toward teaching in "real-life" situations, which will entail the development of "community classrooms" and mentors. In this fashion, our future physicians will be enabled to see and experience the full range of medical endeavor and thereby be better equipped to serve their patients and communities.

Daniel W. Varga, MD

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Distinguished Past . . . Dynamic Future



Gloria J. Griffin

The whirlwind of change in the health care arena surrounds all of us. These winds constantly shift from one direction to another, inciting various responses from organized medicine in order to avoid jeopardizing the highest quality of medical care ever known to the world.

As organized medicine and each of its components realize their individual role and the role of various aspects of the health care system in response to our rapidly changing world, those of us who are devoted to that profession must also assess our organization and, if necessary, reassess its priorities.

In order to properly assess the priorities of an organization, however, it is necessary to know the organization . . . and in order to have a comprehensive knowledge of our organization, it is necessary to know its history.

As the Auxiliary enters its 70th year as an organization in Kentucky, it's helpful to reflect on not only why we are here but how we got here in the first place. In the spring of 1921, Arthur T. McCormack, MD, secretary of the Kentucky State Medical Association, was contacted by Holman Taylor, MD, secretary of the Texas State Medical Association. Dr Taylor had some exciting news about a group of "DOCTORS' WIVES" in Texas. The thread that joined them together was their marriage to a physician, and they were concerned about the image the DOCTORS were receiving because of the charlatans that were coming into their state and the quackery/deception affecting the medical profession in those days. A group of these wives had organized an auxiliary in order to address these concerns. It is interesting that this clearly was not a "social club."

"Our distinguished past is but a forerunner of the dynamic future we have if we all accept the challenge of the 90s, pick up the gauntlet of change, and charge into the fray alongside our spouses in the decade to come."

Dr McCormack was inspired by what was happening in Texas and felt that the "DOCTORS' WIVES" in Kentucky would be inclined to help their physician husbands. He discussed this at great lengths with other physicians from around the state and felt confident that he had enough backing from these physicians and their wives to take this information to the state medical association. The Kentucky State Medical Association council approved Dr McCormack's recommendation to organize the "DOCTORS' WIVES" at the 1921 annual meeting.

While attending the AMA annual meeting in May of 1922, Dr

McCormack met Mrs S. C. Red, the first president of the Texas Auxiliary. Mrs Red spoke during the AMA House of Delegates about the possibility of the AMA organizing a national auxiliary. Dr McCormack was so impressed with Mrs Red's presentation and was confident that the news about the auxiliary would be well received by the "DOCTORS' WIVES" in Kentucky.

In the fall of 1922, Dr McCormack appointed Mrs Frank Boyd of Paducah as chairman of a committee to organize a meeting of the 50 "DOCTORS' WIVES" accompanying their husbands at the state medical meeting. After much discussion, the "DOCTORS' WIVES" said though they were "willing to continue to entertain the men at their annual meetings and country society picnics and suppers, their present duties and inclinations demanded so much of their time that they could see no possibility to undertake new or untried responsibilities." This unofficial "initial agenda" for the organization indicated not so much a lack of enthusiasm on the part of the new Kentucky Auxilians as it did a lack of perception of the value of their participation in the matters of medicine.

At the next state medical association meeting, held in 1923 at Crab Orchard Springs, the Women's Auxiliary to the Kentucky State Medical Association was formalized with the help of the retiring state President, Louis Frank, MD. The first officers were Mrs Graham Lawrence, President, Shelbyville; Mrs C. Z. Aud, Vice President, Louisville; and Dr Annie S. Veech, Secretary, Louisville. They ultimately served for 3 years, while the Auxiliary was in its infancy, organizing a constitution, the bylaws, and collecting dues.

"We cannot afford to allow, by our lack of participation, the restructuring of United States health care to be crafted by those who are not bound by the ethics of the medical profession."

Though begun in Kentucky with the intent of being involved only in social activities, the Auxiliary members, in fact, began to learn more about health and medicine and the impact that they as physicians' spouses could have in assisting the medical profession to achieve its goal of improving the health of the citizenry of Kentucky and the nation.

As early as 1930, "Radio Waves," a weekly program to spotlight aspects of good health, was initiated by the Auxiliary. Over the years, our auxiliaries have publicized multiple public health hazards, fought for better access to health care, distributed information about teen pregnancy, assisted in public vaccination and school health programs, promoted funds necessary for medical research and education, and have become a political force for medicine in the state and throughout the nation.

We are social beings and enjoy the company of one another, but we are not a social club. We are a vital part of the medical profession and have the responsibility to ensure that the progress seen in the health status and quality of medical care in the US is not threatened by outside forces, as we face the changes which will occur in the health care financing and delivery systems over the next few years.

To quote Mrs George Hendon, 1931-32 president of the Women's Auxiliary to the Kentucky State Medical Association, "A nation's chief asset is the health of its inhabitants. The national level of health can only be raised by correlated efforts on the part of organizing forces devoted entirely to that purpose." We cannot afford to allow, by our lack of participation, the restructuring of United States health care to be crafted by those who are not bound by the ethics of the medical profession.

Our distinguished past is but a forerunner of the dynamic future we have if we all accept the challenge of the 90s, pick up the gauntlet of change, and charge into the fray alongside our spouses in the decade to come.

I challenge each of you to commit to the medical profession with the same dedication as your spouse, and to serve that commitment by urging significant activities by your Auxiliary at the local, state and national levels, and by becoming personally involved in those efforts.

For membership information, contact Jean Wayne at the KMA office, 301 N Hurstbourne Pky, Suite 200, Louisville, KY 40222-8512. Phone 502/426-6200; FAX 502/426-6877.

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AWARDS NOMINATIONS

The KMA Awards Committee is accepting nominations for the two highest awards the Association presents. The Distinguished Service Award is presented annually to a member of the Association based on the following criteria:

- Contributions to organized medicine (including membership in county society, attendance of county and state meetings, service on committees, leadership as an officer, etc.)
- Individual medical service
- Community health, education and civic betterment
- Medical research

The nominee may qualify on any one or all combinations of these points. Reasons for the nominations should be clearly stated.

The Kentucky Medical Association Award is presented to an outstanding lay person in Kentucky each year in honor of his or her outstanding accomplishments in the field of public health and/or medical care.

The Awards Committee will have the responsibility to choose recipients of the KMA Distinguished Service Award and the Kentucky Medical Association Award. Any county society or individual member may suggest nominees to the committee.

The awards are presented at the President's Luncheon during the annual meeting.

AWARD NOMINATION FORM

Name: _____

Address: _____

Birth Date: _____ Place: _____

Marital Status: _____

Spouse's Name: _____

Children: _____

☐ Distinguished Service Award (Physician)

☐ KMA Award (Lay Person)

Education: _____

Military: _____

Membership in Professional Organizations: _____

Membership in Civic Organizations: _____

Honors and Awards: _____

(Describe nominees qualifications and other pertinent information which the Awards Committee may consider in making its decision.

Name of Person or Group Submitting Nomination: _____

Address: _____

Phone: (Home) _____

(Office) _____

Please fill in and mail to: KMA, Attn: Awards Committee, 301 N Hurstbourne Pky, Ste 200, Louisville, KY 40222

Deadline for receiving nominations is July 15.

1993

MAY

20-22 — The American Society of Internal Medicine Leadership Development Conference; Mariott Hotel, Portland, Oregon. Contact: Melinda Klein; 202/835-2746, ext 266.

23-28 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

JUNE

10-12 — 38th Great Smoky Mountains Pediatric Seminar; Park Vista Hotel, Gatlinburg, TN. Contact: CME, 1924 Alcoa Highway, D-116, Knoxville, TN 37920; 615/544-9190.

JULY

15-17 — First Annual Mid-South Symposium on Cardiovascular Disease; The Laurence A. Grossman Medical Learning Center, St Thomas Hospital, Nashville, TN. Contact: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; 800/257-4739 (outside the US and Canada, 301/897-2695); FAX 301/897-9745.

SEPTEMBER

18 — Tenth Annual Ophthalmology Seminar: Update on Management of Age-Related Macular Degeneration; Humana Hospital Audubon, Louisville, KY. Contact: Cathy Edens, 240 Audubon Medical Plaza, Louisville, KY 40217; 502/636-2823.

OCTOBER

13-17 — The American Society of Internal Medicine 37th Annual Meeting; J. W. Marriott Hotel, Washington DC. Contact: Melinda Klein; 202/835-2746, ext 266.

31-Nov 5 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

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1993 SCIENTIFIC ASSEMBLY JUNE 10-12

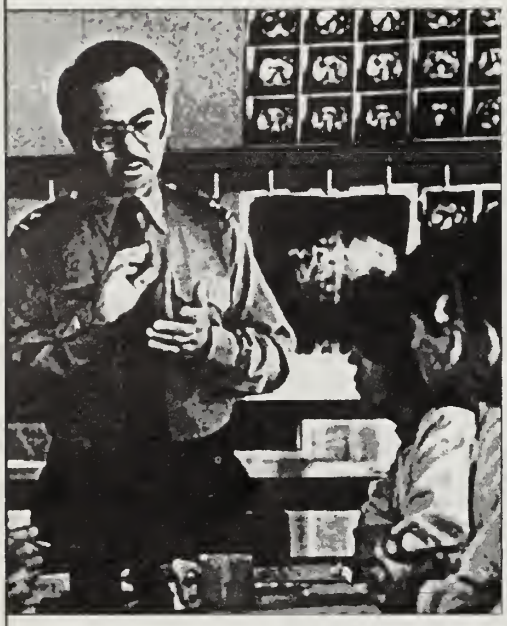
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NOVEMBER

14-18 — 97th Annual Meeting of the American Academy of Ophthalmology; McCormick Place, Chicago. Contact: The American Academy of Ophthalmology, Meetings Department, PO Box 7424, San Francisco, CA 94120-7424; 415/561-8500.

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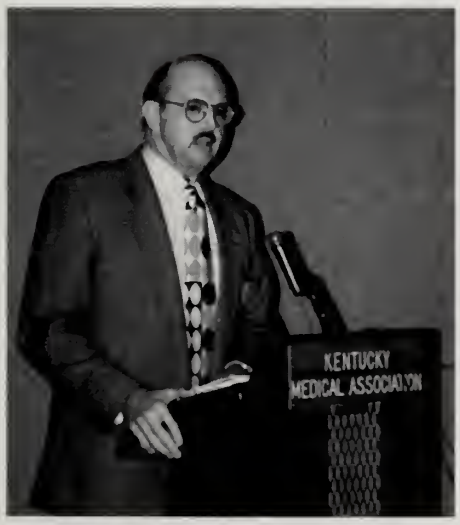
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Specialty Societies Meet on Health Care Reform

Representatives of 15 specialty societies met on March 11, 1993, with the KMA Executive Committee. The purpose of the meeting was to share information about Governor Brereton Jones' proposal for health care reform; to provide an overview of a counter proposal prepared by the Coalition on Health Care Reform, of which KMA is a member; to reacquaint members with the reform proposal KMA submitted last year; and to discuss KMA's plans once the special session is underway. KMA





An excellent representation of the specialty societies heard from KMA Board Chairman Russell L. Travis, MD (L). Pictured at bottom left are KMA President William B. Monnig, MD; Secretary-Treasurer William P. VonderHaar, MD; Vice President David C. Liebschutz, MD; and Board Vice Chairman John W. McClellan, Jr, MD.







PEOPLE

In addition to his duties as KMA 11th District Trustee, **William H. Mitchell, MD,** Richmond, is currently serving as president of three organizations: Kentucky Chapter American College of Surgeons, Hiram C. Polk Surgical Society, and Madison County Medical Society.

The KMA Judicial Council is pleased to report that **Samuel D. Weakley, MD,** Louisville, has recently been appointed to serve on the Council, and that **William P. VonderHaar, MD,** Louisville, was elected Chairman by acclamation. Other Council members are: **Paul J. Parks, MD,** Bowling Green; **Charles R. Sachatello, MD,** Lexington; and **William T. Watkins, MD,** Somerset.

Billy F. Andrews, MD, retired recently after 23 years as chairman of the Department of Pediatrics at the University of Louisville School of Medicine. To mark the occasion, Kosair Charities Committees, Inc donated $100,000 to help endow a chair in his honor. Dr Andrews is internationally recognized as a pioneer in the field of clinical neonatology because of his numerous studies, inventions, and original training programs addressing the care of newborns. Dr Andrews is currently serving as a Visiting Scholar in Medical History and Ethics at Green College, Oxford, England.

Two KMA members recently served on the faculty for the symposium "Thoracic and Cardiovascular Surgery" sponsored by the Southern Medical Association. **Magdalene B. Karon, MD,** spoke on the topic "Cardiovascular Benefits of Hormonal Therapy." Dr Karon, a specialist in obstetrics and gynecology, is in private practice in Lexington. **William D. Newton, MD,** spoke on the topics "Atheroembolism" and "Non-operative Therapy for Peripheral Vascular Disease." Dr Newton, a specialist in vascular surgery, is affiliated with Surgical Associates of Lexington.

UPDATES

Auto Air Bag-Induced Injuries

Auto air bags can cause injuries unless drivers maintain proper driving position, says **William Smock, MD,** of the University of Louisville School of Medicine. Dr Smock, a forensic emergency medicine specialist, found accident victims who grip the steering wheel hub rather than the rim are more likely to suffer finger or hand injuries. Also, serious and potentially fatal head or chest injuries could occur if a driver or passenger sits too close to a deploying air bag.

Kentucky Ophthalmologists Providing Eye Care to Disadvantaged Elderly

The Foundation of the American Academy of Ophthalmology reports that because of a concern that senior citizens are not getting the medical eye care they need, America's Ophthalmologists established the National Eye Care Project℠, a nationwide outreach program.

More than 3,302 disadvantaged, elderly Kentucky residents have called the Helpline of the National Eye Care Project℠ for assistance with eye problems since it began operation in 1986. In Kentucky, the program is sponsored by the Kentucky Academy of Eye Physicians and Surgeons and the Foundation of the American Academy of Ophthalmology.

"It is our goal as ophthalmologists to make all aspects of medical eye care both accessible and affordable to ensure that every elderly American has access to the highest quality of eye care," said **Richard A. Eiferman, MD,** president of the Kentucky Academy of Eye Physicians and Surgeons.

To qualify for a referral through the National Eye Care Project℠, the patient must be a US citizen or legal resident, 65 or older, who does not have access to an ophthalmologist she or he has seen in the past. The toll-free Helpline number is 1-800-222-EYES (1-800-222-3937). The Helpline operates weekdays, 8 AM to 4 PM Pacific time.

U of L Physicians Modernize Burn Care in Vietnam

The University of Louisville reports that a team of their physicians recently went to Vietnam to teach health care professionals how to save burn victims from often-fatal infections.

Plastic surgeons **Larry D. Florman, MD,** and **Gordon R. Tobin, II, MD,** are team leaders of the Louisville Burn Project.

The team trained 500 Vietnamese medical workers in modern burn-treatment techniques, helped open four regional burn centers, and performed reconstructive surgery on patients.

Other participants are **Benjamin M. Rigor, MD,** chairman of the U of L anesthesiology department; Elisabeth (Mrs Gordon R. II) Tobin, a bacteriologist; and nurse Evelyn McAfee, a specialist in children's burns.

The U of L plastic surgery department pioneered many of the special types of burn treatment that have become widely accepted, Dr Tobin said. He cited several examples, including skin grafting techniques, early removal of burned tissue to lessen infection, and reconstructive surgery.

Dr Florman said that Vietnam has no hospital units set aside for burn patients. The group helped open burn centers in Hanoi, Danang, Ho Chi Minh City, and Con Tu Province.

Dr Florman plans a 3-year project. He and Dr Tobin would like to see U of L residents and medical students as part of the team. Dr Tobin said expansion of the project is contingent on obtaining funding.

Technology Brings New Way to Monitor Anesthesia

U of L researchers are using patients' hearing to help in administering anesthesia. According to a report from the University, anesthesiologist **Harvey L. Edmonds, MD,** and information technology researcher Ted Strickland have devised a system that uses auditory signals — clicks in the patient's ears — to measure brain waves which reflect the patient's level of consciousness.

Since hearing is the last sense lost before and the first recovered after anesthesia, the monitor helps doctors ensure the patient doesn't wake up during surgery.

The researchers determined that using an auditory-evoked potential such as the clicking in the ears throughout the surgery would produce brain waves that could be monitored.

The lower the brain waves, the deeper the unconsciousness.

When brain waves start to increase, the anesthesiologist knows the patient is awakening.



KMA President William B. Monnig, MD, accepted a membership award on behalf of KMA at the AMA National Leadership Conference. KMA increased its AMA membership by almost 8% overall for 1992, the Second Consecutive Prior Year that the Association has surpassed its previous year's record of AMA members. Currently, 56% of KMA active members belong to the AMA.

Presenting the award to Dr Monnig were AMA President John Clowe, MD (L), and AMA Board of Trustees Chairman Raymond Scalettar, MD (R).

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Fayette

Purnima Dixit, MD — AN
3320 Tates Creek Rd #204, Lexington, 40523
1984, U Tennessee

Robert T. Grant, MD — ORS
601 Perimeter Dr #200, Lexington 40517
1981, U of Southern Florida

Vipul N. Mankad, MD — PD
UKMC Pediatrics J406, Lexington 40536
1966, Majaraja Sayaji Rao U

Lenora Phillips, MD — P
PO Box 12148, Lexington 40581
1979, U of Southern Alabama

Harlan

Joseph N. Dytoc, MD — GE
94 Ballpark Rd, Harlan 40831
1981, U of Santo Tomas

Jefferson

Kenneth L. Balcombe, MD — OTO
1169 Eastern Pky #1234, Louisville 40217
1982, U of Saskatchewan

Denver B. Cornett, III, MD — PD
4010 Dupont Cir #L-3, Louisville 40207
1987, U of Louisville

Cindy L. Corpier, MD — NEP
500 S Floyd, Louisville 40202

1984, LSU School of Medicine
James L. Cowan, III, MD — PD
2120 W Chestnut #C, Louisville 40211
1987, Meharry Medical Col
Lisa A. Crawford, MD — OBG
3 Audubon Pl #110, Louisville 40217
1988, U of Kentucky
Mushtaque M. Juneja, MD — AN
7372 Wolfspring Tr, Louisville 40241
1972, M P Shah Medical School
Karen W. Krigger, MD — FP
2126 Oregon Ave, Louisville 40210
1988, U of Louisville
Robert M. Lindner, MD — U
6400 Dutchmans Pky #340, Louisville 40205
1987, Wayne State
Michael T. Macfarlane, MD — S
250 E Liberty #602, Louisville 40202
1983, Columbia U
James W. Mold, MD — FP
1019 Springside Way, Louisville 40223
1974, Duke U
Sean F. Murphy, MD — OPH
8009 Albrecht Cr, Louisville 40241
1985, Wayne State
William M. Roberts, MD –AN
709 N Arbor Dr, Anchorage 40223
1986, U of Louisville
David P. Rouben, MD — ORS
9822 Old Third St Rd #310, Louisville 40272
1977, U of Louisville
Michael A. Samuel, MD — AN
3128 Sunfield Cr, Louisville 40241
1988, U of Louisville
Andre R. Thebert, MD — R
1170 E Broadway #201, Louisville 40204
1986, Medical Col of Wisconsin
John J. Vaughan, MD — ORS
11517 Spring Heath Ct, Louisville 40223
1987, U of Louisville
Mark A. Wilson, MD — S
5523 Apache Rd, Louisville 40207
1985, NJ Medical School

Laurel

Jeanetta Lee Rodgers, MD — FP
509 E Ninth St, London 40741
1986, U of Louisville

Letcher

Ni-Kang Der, MD — AN
550 Jenkins Rd, Whitesburg 41858
1964, Taiwan U

Marion

Richard V. Steeves, MD — OBG
130 Country View Dr, Lebanon 40033
1980, U of Western Ontario

Northern Kentucky

Leslie F. Gunzenhaeuser MD — AN
525 Alexandria Pk, Southgate 41076
1977, Ohio State U

Pulaski

Marilyn L. Conner, MD — GP
1900 Gilliland Ln, Somerset 42501
1986, UCLA

Scott

Kristy K. Menke, MD — PD
107 Lankford Dr, Georgetown 40324
1989, Indiana U

Warren

Michael S. Barnett, MD — P
720 2nd St, Bowling Green, 42101
1974, Temple U

In-Training

Fayette

Susan B. Coleman, MD — OBG
Thomas E. Menke, MD — ORS

Jefferson

Melanie Adams, MD — PD
Patricia V. Chandler, MD — P
K. Kent Chevli, MD — S
Diane Francoeur, MD — OBG
Scott R. Jahnke, DO — PMR
Lisa A. Wills-Frank, MD — IM

St. Elizabeth's

Chuc Phuc Le, MD — FP

DEATHS

A. Thornton Scott, MD
Lexington
1908-1993

A. Thornton Scott, MD, a retired internist, died February 6, 1993. Dr Scott graduated from Cornell University School of Medicine in 1934 and was a life member of KMA.

James W. Miller, MD
Greensburg
1907-1993

James W. Miller, MD, a retired general practitioner, died March 4, 1993. Dr Miller graduated from the University of Louisville School of Medicine in 1933 and was a life member of KMA.

Earl D. Rees, MD
Lexington
1928-1993

Earl D. Rees, MD, an endocrinologist, died in a tractor accident on March 14, 1993. A 1954 graduate of Yale University School of Medicine, Dr Rees was an active member of KMA.

Rankin C. Blount, MD
Lexington
1908-1993

Rankin C. Blount, MD, an internist, died March 18, 1993. Dr Blount graduated from Vanderbilt University School of Medicine in 1933 and was a life member of KMA.

DIAGNOSIS &



MANAGEMENT:

SPECIAL ISSUES

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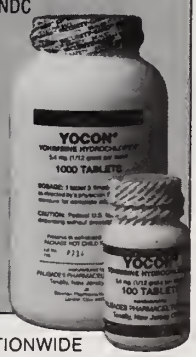
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin, the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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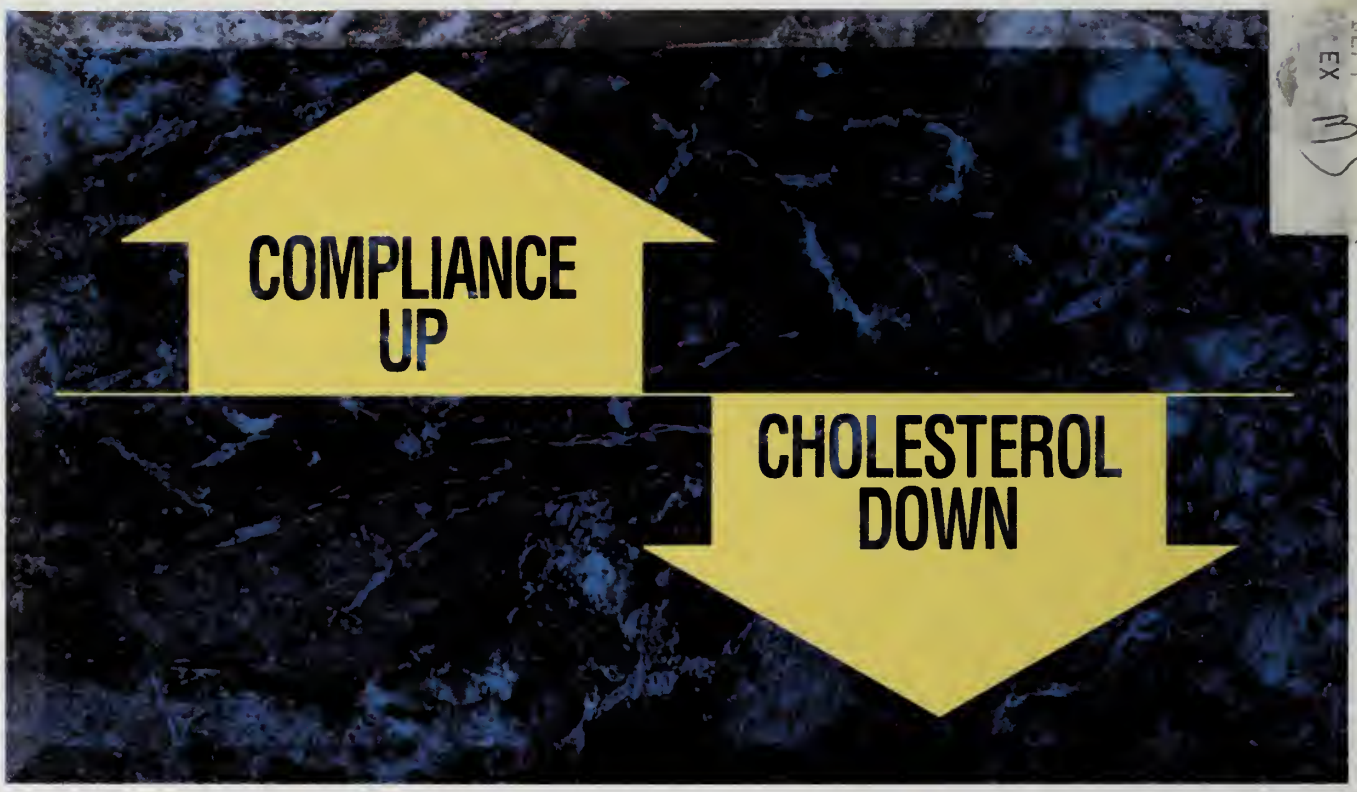
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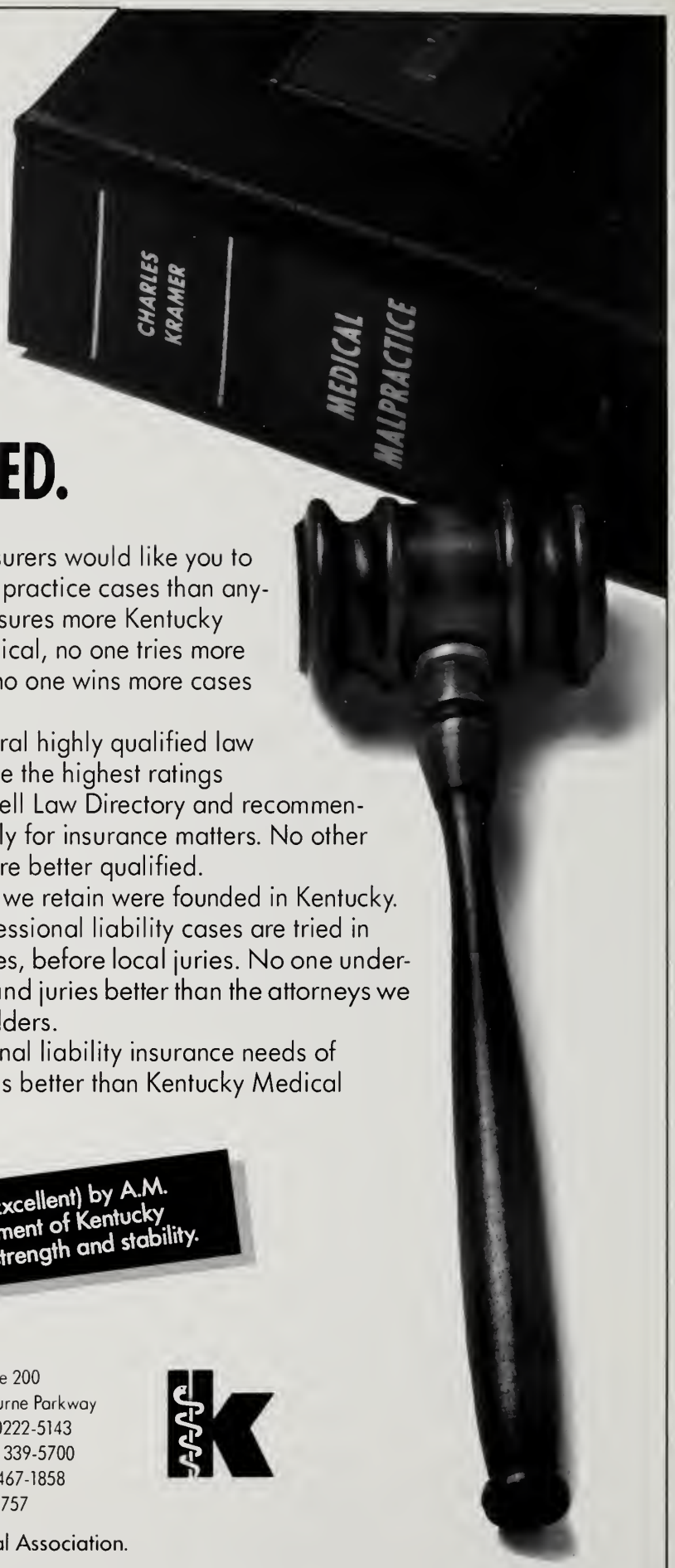
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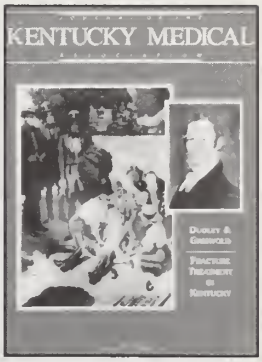
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COVER: Dr Benjomin Winslow Dudley (1785-1870) is pictured in the inset photo ond olso in the photo of o duel in which he participoted in 1818. Dr Dudley ond Dr R. Arnold Griswold ore recognized to hove mode significont contributions to the core of froctures, ond their opinions ore still volued throughout the US. To learn more obout these eminent medicol pioneers, reod the ortiCle beginning on poge 226.
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Health Care Reform



Donald C. Barton, MD

As we all presumed, 1993 is a "crisis year" in American medicine. We are being besieged on all fronts by health care reform and cost containment with the programs being presented on both the state and national level. American medicine, as we now know it, will never be the same after it is all done. Make no bones about it — Health Care Reform to the politicians means one thing only — cost containment. No one will deny that we have the best health care system in the world. It will be up to us to continue to be patient advocates in order to maintain quality care and preserve what is right in our system. Each and every one of us must be involved and vocal in this effort if we are to be successful in this endeavor.

I have just returned from Washington where I attended briefings from the Administration and the Congressional leadership from both parties. Although the Clinton plan is not known at this time, it probably will be by the time you read this article. Then you can compare what their plan says with what we were promised. The AMA leadership has been meeting frequently with administration officials and espousing our viewpoints.

Specifically, we have asked for legislative initiatives to provide clarification of the antitrust laws so that we are able to participate in the system in a way that promotes competition and thereby contributes to the delivery of affordable medical services and enables us to fulfill our historic role as advocates for our patients. We were promised this relief by the Vice-President and Congressional leadership.

We have stressed professional liability reform and administrative cost reduction, with real relief from overregulation. This also was promised to us.

In addition, we were promised freedom for patients to choose their own physician and system of health care delivery, ie, multiple choice of plans.

It seems that the heart of the plan will be managed competition, whatever that means. I predict that the plan will include global budgets and price controls of which the AMA is strongly opposed. The AMA does support negotiated budget predictability, sensitive to demographic, disease, and technological changes, as an alternative. This would provide physicians an opportunity to analyze causes of spending increases.

Other points in the AMA plan include: universal access to care, through an employer mandate and Medicaid reform; insurance market reforms, particularly community rating and eliminations of pre-existing condition restrictions; quality assurance through practice parameters and outcomes research; and establishment at the federal level of an essential benefits package (with repeal of state mandates).

These policies were established by our AMA House of Delegates. A lot of the refinements were hammered out at the last House meeting in December. I want to personally thank the rest of our AMA delegation for the great job they do on your behalf. They work long hours with reading, discussion, and debate and are to be commended for their effort.

"American medicine, as we now know it, will never be the same after it is all done. . . . It will be up to us to continue to be patient advocates in order to maintain quality care and preserve what is right in our system."

If you are not a member of the AMA, then I feel you are shirking your responsibility as your patient's advocate. There is no question that the AMA is medicine's spokesman on the national level, and every physician in the country should be a member.

Thank you for allowing me to serve you.

Donald C. Barton, MD
Senior AMA Delegate





Dudley and Griswold: The Development of Fracture Treatment in Kentucky

Dorothy Richardson, MA; David Seligson, MD

The surgical record of the great state of Kentucky is impressive and one to be admired. Two Kentucky physicians helped pave the way to the modern treatment of fractures. Doctors Benjamin Dudley and R. Arnold Griswold contributed unique ideas and opinions to the practice of orthopaedic surgery. Their techniques and practices were ahead of their times, and today we see a little of each in our everyday treatment of fractures.

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There have been many advancements in the treatment of orthopaedic injuries over the last century. During this period, two Kentucky physicians are recognized to have made significant contributions to the care of fractures. Drs Benjamin Dudley and R. Arnold Griswold were great leaders in their day. These two men were "not only the most eminent and successful operators of their day; but also men of profound thought and research."[1] They introduced new ideas to the practice of surgery and their opinions were valued throughout the United States.

Dr Dudley was the premier surgeon of his day. He was known to be calm with good judgement, especially in pressure situations. It is said that "amidst the heart-rendering screams of his patients, he was never thrown off balance, but would remark: 'Let them scream — it is a relief of nature.' But when the patient was unable to stand further the pain of the operation and struggled, a command would be uttered in a voice not to be misunderstood: 'Be still, Sir, or I'll send your soul to Hell in half a second.'"[2]

Dudley promoted the use of compression bandaging as a means of controlling swelling in the treatment of wounds, fractures, and dislocations.[3] His *roller bandage* was made of prepared canvas which was used to wrap the injured area. With proper application, the *roller bandage* provided "equal compression at all points": the muscles of the limb were constrained to a "perfectly passive state." This eliminated pain often caused by isolated pressure and muscle spasms.[4] Dudley advocated this type of bandaging for most limbs. It was also used for other conditions, such as "gunshot wounds, acute and chronic inflammation, ulcers, milk-leg, lacerations and contusions of all kinds and extent, amputations, and aneurysms."[2] In his use of the *roller bandage*, Dudley's treatment was a forerunner of modern fracture care with cast bracing.

Benjamin Winslow Dudley (1785-1870), lithotomist and frontier surgeon, was born in Spottsylvania County, Virginia, April 12, 1785 (Fig 1). His family moved to Fayette County, Kentucky, when he was a year old. As a teenager, Benjamin became interested in medicine, so his father allowed him to observe the practice of a well-known physician, Dr Frederick Ridley. This experience is said to have provided him with the enthusiasm which characterized his life and practice.[5]

For nearly 50 years, Dr Dudley had almost complete control of surgery west of the Appalachians. Not only was he known as a skilled surgeon, but also his opinions were valued nation-

Fig 1 — (Inset) Dudley, Benjamin Winslow (1785-1870). Courtesy of Kornhauser Library, University of Louisville.

Fig 2 — The duel of 1818. Dr Dudley stepped forward and asked if he might be permitted to stop the flow of blood. He put pressure over the femoral artery and the bleeding stopped. Courtesy of Kornhauser Library, University of Louisville.



Fig 3 — Rettig Arnold Griswold (1898-1972). Courtesy of Kornhauser Library, University of Louisville.

wide. It was during this time that Lexington considered itself to be the "Athens of the West, as a center of classical, legal, and medical education, and of wealth and refinement."[1]

In March of 1806, Dudley received his medical degree from the University of Pennsylvania. He then returned to Lexington to begin practice. In 1809, Transylvania established a course in medicine and appointed Dudley as the chairman of anatomy and physiology. In order to expand his education in this area, he spent most of the next 4 years studying in Paris. In search for additional surgical training, Dudley left Paris for London. These experiences in Europe provided the basis of his subsequent success. "In his manners he was French, in methods English."[6] He returned to Lexington in the summer of 1814, a member of the Royal College of Surgeons. A year later, he was appointed professor of surgery at Transylvania University.

The medical school at Transylvania University, had numerous "personality clashes" which resulted in disagreements among its faculty; the most famous was the duel in 1818 involving Dr Dudley (Fig 2).[7] The cause of the duel began when some medical students of Dr Dudley were arrested for digging up the body of a recently deceased Irishman from a Baptist cemetery. At that time in history, "no law existed to declare bodies private property, so the students were only fined one cent for trespassing and stealing part of the earth which they dug up." The entire incident troubled Dr Daniel Drake, who publicly criticized and insulted Dudley, who responded with a challenge to duel. Drake's good friend, Dr Richardson, accepted the challenge for him.[8,9] Arrangements were made and pistols were selected as the weapons. After gunshots were fired, Dr Richardson was found seriously wounded. His femoral artery was severed and bled profusely. After a tourniquet and other attempts were ineffective, Dr Dudley stepped forward. He applied direct pressure over the femoral artery which stopped the hemorrhaging so the artery could be ligated.[9,10,11]

In many respects, Dudley was ahead of his time. He emphasized the importance of sterilization and preoperative patient care. Dudley realized that dirt and contaminated water played a major role in the onslaught of disease. This idea came years before the science of bacteriology evolved. He believed "boiling the water would rid it of its impurities." This information was particularly valuable during the cholera epidemic in Lexington (1832) when those who followed his advice escaped.[2,12] It was common practice for Dudley to use copious amounts of boiled water during surgery and on various wounds.[2,3]

Dudley attributed his surgical success to the emphasis he placed on preoperative care.[10] This belief set him aside from other doctors of his time. He felt that the preparation for an operation was critical to a patient's recovery and considered it "even more important than the greatest skill in the use of instruments." In regards to Dr Dudley, an Englishman remarked: "It has been reserved for a backwoods man in America to teach how to prepare the patient for a capitol (sic) operation."[12]

Rettig Arnold Griswold (1898-1972) grew up in Peru, Indiana, and to his friends he was known as "Gris" (Fig 3). His father, like his father before him, was a surgeon. He was a railroad surgeon and it was by being around his practice that "Gris" became interested in fractures.

Well into the 20th century, operations were often performed in the patient's home. Griswold's

"earliest surgical recollections were of watching and later assisting his father under such circumstances. The patient would rest on the kitchen table or on a window shutter supported by two chairs. The few instruments available were boiled on the kitchen stove and the field was "draped with sheets sterilized in bichloride solution."[14] These experiences provided Griswold with the inspiration to pursue a career in medicine.

After graduating from Howe Military School in 1916, he entered Harvard. In April 1917, he left Harvard to fight in the war as an aircraft pilot for the Navy. He received several decorations. It is joked that the German army tried to give him an Iron Cross because of the number of planes he wrecked.[15, 16, 17]

After the war, Griswold returned to Harvard and received his bachelors degree in 1921. He continued his education at the University of Louisville School of Medicine, graduating in 1925. He spent the next 7 years in training, studying pathology, clinical surgery, radium therapy, and surgery. In 1932 he became associate professor of surgery at the University of Louisville. Six years later he was appointed professor and chairman of the department. In 1942 he was commissioned as Major in the Medical Corps and was assigned as consultant in surgery to the Fourth Service Command. A year later he was transferred to Walter Reed Hospital as chief of surgery, which made the staff "a sort of informal University of Louisville medical club" since it was composed of a number of former University of Louisville faculty members. After 2 years he returned to the University of Louisville as the head of the surgery department. The place was disorganized since most of the faculty had been in the service. "Gris" started to rebuild the program. He soon incorporated a plan where students and residents rotated through the Veterans Administration hospital. This program contributed immensely to maintaining "high standards of patient care."[15]

Dr Griswold was a "leader and innovator." He published over 50 papers in top journals and was active in 15 national surgical organizations. His contributions to the treatment of fractures were enormous. He invented a skeletal traction machine, the "Griswold Machine," and was an early advocate of the hanging cast for fractures of the humerus. He strongly supported the use of the shoulder harness seat belt in Kentucky, and successfully reinfused blood from the abdomen in trauma patients. Due to Dr Griswold's accomplishments, the Louisville City Police Department selected him to train their emergency medical personnel.[16] This relationship between EMS and Louisville Trauma Surgery continues today.

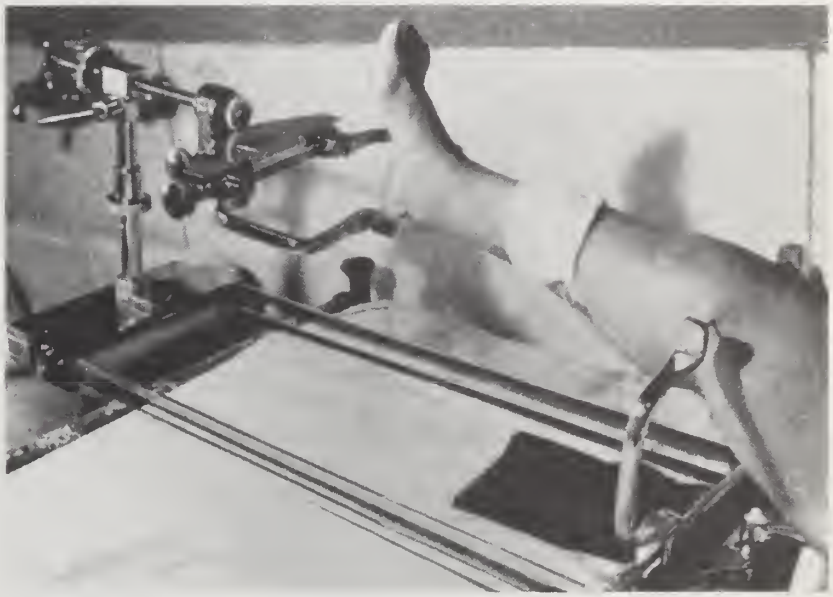


Fig 4 — The "Griswold Machine." Patient in the apparatus for fracture reduction. Courtesy of JAMA.

The "Griswold machine" is an "external scaffold" which reduces a fracture until repair is complete (Fig 4). The device "supplies skeletal traction and counter-traction with accurate mechanical control of both proximal and distal fragments," and "when necessary, can be supplemented by either a non-padded plaster cast or steel pins which transfix both fragments."[18, 19, 20] The result is early use of the extremity and the ability for weight-bearing.

"Gris" believed the most important goal in surgery was to restore the patient back to normal function. This depended on maintaining the integrity of the skeleton and motion of the surrounding soft tissues. He was guided by two fundamentals in the treatment of fractures; first, "all the bones consolidated more slowly if not laid properly, and if not kept steady in the same position"; and second, "exercise strengthens and inactivity wastes."[14, 18, 19, 21]

These same principles are demonstrated in Griswold's treatment of fractures of the humerus. The patient was told to actively exercise the injured part once the casting plaster had dried. The active exercise was shown to prevent as well as reduce swelling at the fracture site. The patients

with fractures of the upper extremity were taught to "completely open and close the fist, button clothing, write, light cigarettes, sweep or do other exercises appropriate to his habits or occupation" on the day of the injury.[20]

"One morning after doing a gallbladder, a hysterectomy, and fixing a fracture, one of his highly specialized friends asked him what kind of 'damn surgeon' he was, anyway. He retorted, 'Hell, I'm a vascular surgeon, I cut 'em where they bleed.' " One of Dr Griswold's residents described working under "Gris." "He demanded perfection and occasionally got it. When he didn't, he could take the hide off your back as expertly as a mule skinner, but he did it in a way that didn't anger us but made us determined to do better. Further, it was kept in the family. To others he proclaimed loud, long, and frequently that he had the 'best damned residents' in the business. We, in turn, knew that he was always for us. He must have stayed up many a night figuring out how he could throw opportunities our way for advancement and development. We all feel that we owe to him a good measure of any success we may have had."[15]

"Only two states in the Union, New York and Massachusetts, have a greater heritage in orthopaedic surgery than Kentucky."[22] Here we have found two surgeons who by either accident or innate ability seized some of the essence of modern fracture care years before the principals underlying them had been revealed. Drs Dudley and Griswold stand in a class by themselves. The history of fracture treatment in the great state of Kentucky is one that can be looked upon with pride.

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Dissecting Aortic Aneurysm Mimicking Massive Pulmonary Embolism

Miguel A. Ossorio, MD; Sheila A. O'Grady, MD; Thomas M. Roy, MD; Cheryl L. Fields, MD

The finding of a massive unilateral segmental defect with normal ventilation upon lung scanning does not always secure the diagnosis of acute pulmonary embolus. We present a patient whose ventilation-perfusion lung scan suggested a significant embolic phenomenon, but who was subsequently found to have compression of her right pulmonary artery by a dissecting aortic aneurysm. Conditions that present with a unilateral perfusion defect merit further evaluation with pulmonary arteriography.

Ventilation-perfusion lung scans have been utilized as a diagnostic tool in the evaluation for suspected pulmonary embolism for over a decade.[1] Multiple prospective studies have suggested that no further diagnostic studies for pulmonary embolism are necessary when one or more segmental or greater perfusion defects are discovered with normal ventilation.[2] However, when the lung perfusion defect of segmental or greater magnitude without a concurrent ventilation abnormality is unilateral in presentation, other non-thromboembolic phenomenon should be considered in the differential diagnosis.[3,4] In this instance, further diagnostic studies are warranted, including pulmonary angiography. We present a patient in whom the ventilation-perfusion lung scan supported the diagnosis of a massive pulmonary embolism, yet on angiography was found to have a dissecting aortic aneurysm with right pulmonary artery compression.

Case Report

A 44-year-old black female with essential hypertension and congestive heart failure presented to the emergency room with chest pain of several hours duration. The substernal sharp chest pain was abrupt in onset and radiated down her right arm. The patient experienced nausea with one episode of emesis. Vital signs were stable. Auscultation of her lung fields was remarkable for scattered rhonchi posteriorly. The patient's heart sounds were distant. A grade 1/6 nonradiating diastolic murmur was appreciated at the left sternal border. Peripheral pulses were symmetric. Pretibial pitting edema was noted in the lower extremities.

The electrocardiogram obtained in the emergency room showed a sinus rhythm with a previously noted first degree heart block. Serum CPK and LDH levels were not elevated. An elevated right hemidiaphragm with a prominent right pulmonary artery was seen on chest radiograph. The heart appeared enlarged without mediastinal abnormality.

The initial impression was that of an evolving myocardial infarction. The patient was admitted to the Cardiac Intensive Care Unit where nitroglycerin and heparin drips were instituted. The patient's pain diminished. Within 24 hours, cardiac isoenzymes failed to confirm an acute myocardial injury and both medications were discontinued. Less than 12 hours later, the patient experienced a new episode of similar chest pain with significant shortness of breath. An arterial blood sample revealed her PO_2 to be 50 mm Hg while on two liters of oxygen via nasal cannula. This was a significant decrease from her admission arterial oxygen level of 68 mm Hg at room air. The diagnosis of pulmonary embolism was considered likely and the heparin drip was reinstituted.

A technicium-99m perfusion lung scan was obtained which demonstrated a complete lack of

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Fig 1 — Technicium-99m perfusion lung scan demonstrating total lack of perfusion of the right lung with no abnormalities in the left lung.

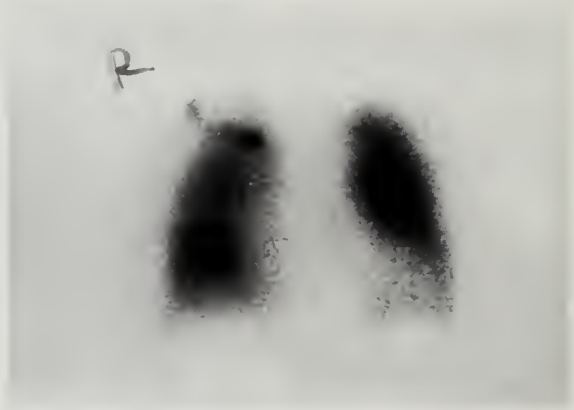


Fig 2 — Xenon ventilation study demonstrating normal ventilation of the right and left lungs.

perfusion of the right lung (Fig 1). The ventilation phase was intact (Fig 2). This study was considered indeterminate and pulmonary angiography was arranged. A type I aortic dissection of the ascending aorta with extrinsic compression of the right pulmonary artery was demonstrated. The dissection extended from an entry point above the sinuses of Valsalva in the proximal ascending aorta to the level of the iliac bifurcation. The patient was spared potentially harmful thrombolytic therapy and underwent acute surgical repair of this dissecting aortic aneurysm.

Discussion

The presence of segmental or greater lung perfusion defects with normal ventilation is deemed by most investigators to indicate a greater than 80% probability for pulmonary embolism.[2] Often this observation will negate the need for further diagnostic testing. However, this clinical and radiographic combination may be mimicked by a variety of non-thromboembolic phenomenon.[3,4] When a segmental or greater ventilation-perfusion mismatch is only unilateral in presentation, other pathologic processes should be considered in the differential diagnoses.

The occurrence of unilateral absence of pulmonary artery perfusion by lung scanning is uncommon and occurs with an incidence of only 2% in major studies.[3,4] Pathologic processes that result in unilateral lung perfusion defects are listed in Table 1.[3,4] The occurrence of a pulmonary embolus producing a unilateral perfusion defect varied from 6% to 23%.[3,4] When such a significant unilateral defect is found by perfusion lung scanning, the diagnosis of pulmonary embolism cannot be presumed and further diagnostic testing is warranted.

The true incidence of pulmonary artery compression by a dissecting aortic aneurysm is not known. Aortic aneurysm dissection as a cause of pulmonary artery compression first appeared in the medical literature in 1944.[5] Over 100 cases of pulmonary artery compression in this manner have since been reported in the medical literature, but the majority were discovered at autopsy.[6-15] Yet, in a retrospective analysis at autopsy of aortic dissection in 62 patients, pulmonary artery compression was not found.[16]

Right pulmonary artery occlusion secondary to ascending aortic dissection is the more commonly reported manifestation.[6-13] The adventitial hemorrhage that occurs in the ascending and

Table 1. Entities causing massive unilateral perfusian defects

Branchagenic carcinama
Cangenital heart disease fallawing shunt pracedures
Parenchymal lung disease
Unilateral bullaus emphysema
Unilateral pulmanary artery agenesis ar stenasis
Fareign body
Mucus plug
Inflammatary lung diseases with mediastinal ar hilar adenapathy (Tuberculasis, sarcaidasis)
Dissecting aartic aneurysm
Pulmanary embalism

transverse aorta and pulmonary trunk with dissection leads to extrinsic compression of the right pulmonary artery as it passes between the aorta and left atrium.[10] Most cases occur with acute rather than chronic aortic dissection. This is in contrast to left pulmonary artery occlusion. The relatively infrequently reported left pulmonary artery occlusion is related in most cases to an indolent syphilitic aneurysm occurring in the descending aorta.[14,15] The pathogenesis of the unilateral defect is also presumed to be extrinsic compression.

The clinical and radiographic presentation of aortic dissection with pulmonary artery occlusion may mimic that of pulmonary embolism. The clinician and radiologist should be alerted to possible non-thromboembolic causes when a significant unilateral segmental lung perfusion defect presents. Further diagnostic testing with pulmonary angiography prior to institution of life-threatening therapy is indicated when this pattern occurs.

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Irradiation in the Management of Anal Cancer With Literature Review

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Sixteen patients with a diagnosis of anal cancer were treated from 1981 to 1990 with combination of surgery, irradiation, and chemotherapy. Median age was 56 years (range 42 to 78 years). There were 3 males and 13 females. Fourteen patients were white and 2 were black. The stage of the primary was: T_1-4, T_2-9, T_3-3. Eleven patients had the tumor in anal canal and 5 patients at the anal verge. Twelve patients had squamous cell carcinoma and 4 had cloacogenic carcinoma. Four patients had planned abdomino perineal resection (APR) after pre-operative chemotherapy (mitomycin C-15 mgm/m² day 1; 5-fluorouracil, 750 mgm/m², 24 hour infusion, days 1 to 5, repeated q15 days), and irradiation (30 gy in 15 fractions in 3 weeks). One patient had wide excision of the primary site after the pre-op chemotherapy and irradiation. Ten of 11 patients received higher dose of irradiation (45 to 55 Gy in 4½ to 5½ weeks, 5 days/week) in combination with chemotherapy and anal sphincter conservation surgery. One patient refused chemotherapy and was treated with surgery and high dose irradiation. The median follow-up was 28 months (range 3-125 months). Fifteen patients (94%) had local control. Thirteen are NED from 3 to 125 months and 2 died of intercurrent disease without cancer at 3 and 14 months. One patient with local recurrence at 9 months had salvage surgery, but died of disease. Except for moderate diarrhea and perineal reactions, there were no major complications. Combination of surgery, irradiation, and chemotherapy provides good local control of the disease in anal cancer, and by using higher dose of irradiation, radical surgery can be avoided. Data from larger studies such as RTOG-8704 are needed to confirm this finding.

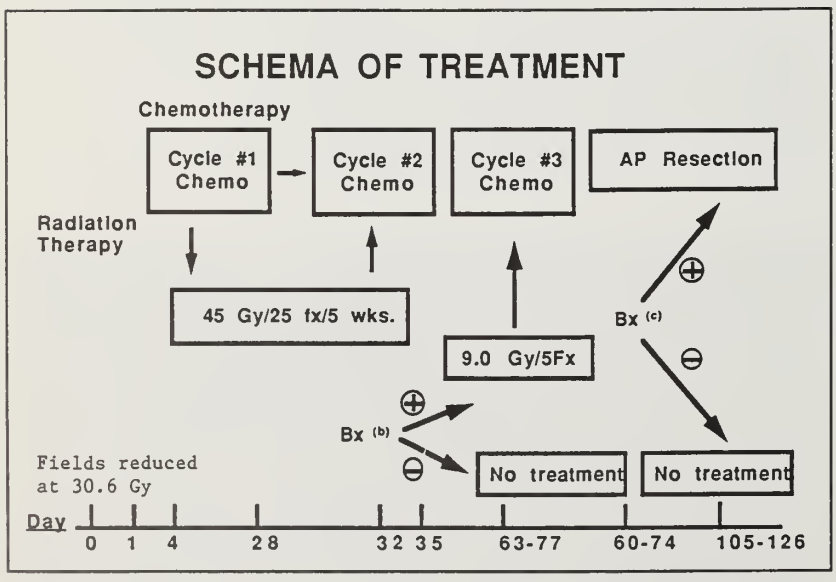


Fig 1

The management of anal cancer with combinations of surgery, irradiation, and chemotherapy has evolved for the last few years and many reports have been published.[1-58] Surgical procedures that affect the anal continence are generally reserved for patients who fail after irradiation and chemotherapy. There are still differing opinions on the optimum irradiation and chemotherapy protocols. The intent of this publication is to report on the results of 16 patients treated in our department from 1981 to 1990, with brief review of the literature.

Subjects and Methods

Sixteen patients with a diagnosis of anal cancer were treated with combination of surgery, irradiation, and chemotherapy. Thirteen of the patients were female (Table 1). The median age was 56 years. Eighty-one percent of the patients had the primary tumor of stage T_1 and T_2 (Table 2). Seventy-five percent of the patients had squamous cell carcinoma (Table 3). Eleven patients had the cancer in the anal canal and five patients at the anal

Table 1. Clinicol Doto

Number of potients		16
Gender	Femole	13
	Mole	3
Roce	White	14
	Block	2
Medion oge		56 yrs (42 yrs-78 yrs)
Site	Conol	11
	Verge	5

Table 2. Stoge of Anol Concer

Tumor	# of Potients	Percent
T_1	4	25
T_2	9	56
T_3	3	19
	16	100

Only 2 Potients hod Nodol Diseose ot Diognosis

Table 3. Histologicol Types

Type	# of Potients	Percent
Squomous cell corcinomo	12	75
Cloocogenic corcinomo	4	25
	16	100

verge. Four patients had a planned abdomino perineal resection after the preoperative combination chemotherapy and irradiation (Tables 4-5). One patient had wide excision of the primary tumor after the pre-operative chemotherapy and irradiation. Ten of 11 patients received higher dose of irradiation (45 to 55 Gy in 4 1/2 to 5 1/2 wks, 1.8 Gy/Rx, 5 days/wk) in combination with chemotherapy and anal sphincter conservation surgery similar to the RTOG 87-04 and ECOG 1289 protocols (Fig 1). The fields were reduced at 30.6 Gy by lowering the top border of the pelvic field from L5/S1, junction to the lower border of sacroiliac joints (Tables 6-7, Fig 1). One patient refused chemotherapy and was treated with surgery and high dose irradiation. The patients were closely followed for acute and late side effects and for local control of the disease.

Table 4. Types of Surgery

Type	# of Potients	Percent
Biopsy	11	69
Wide excision ofter pre-op, chemo ond RT	1	6
Abdomino perineol resection ofter pre-op, chemo ond RT	4	25
Totol	16	100

Table 5. Pre-Operotive Regimen

1. Mitomycin-C — 15 mgm/m^2 on Doy 1
2. 5-Fluorourocil — 750 mgm/m^2
 24 hour infusion on doys 1-5
 repeot cycle — Q 15 doys
3. Irrodiotion — 30 gy in 15 fxs in 3 weeks

Table 6. Chemotheropy Cycles 1 & 2

Arm 1: 5 FU 1000 mg/m^2/24 hrs
Continuous IV for 96 hours, Doy 1 ond Doy 28 of RT.

Arm 2: 5 FU os obove + mito C: 10 mg/m^2 IV bolus 1 of eoch 5 FU course (mox 20 mgs per cycle)

Table 7. Solvoge Theropy

Chemo (cycle 3)	5 FU os obove. Storting within 2 weeks of biopsy. CDDP 100 mg/m^2 IV over 6 hrs on doy 2 of RT (if creotinine < 50 substitute mito C).
Rodiotion	9.00 gy boost RT with electron/photon beom on perineum/inguinol nodes/both.

Table 8. Results

- Medion follow-up — 28 months
- Ronge — 3 months–125 months
- Number of potients olive — 13
- Number of potients olive ofter 2 yrs — 8
- Locol control — 15/16 (94%)
- Deod of intercurrent disease without concer (infection — 1, metobolic — 1)

Results

The median follow-up was 28 months (range 3 months-125 months) (Table 8). The local control

Table 9. Selected Rodiotion Theropy Results

Reference	Treotment	Potients	Primory tumor control %	Complicotions requiring surgery %	Survivol
Popillon[36]	Interstitiol 60 Gy	88	86	5	68% 5 yr crude
Popillon ond Montborbon[37]	Externol 42 Gy/19 doys +20 Gy Interstitiol (some plus 5FU-MMC)	159	88	3	65% 5 yr crude
Doggett et ol[10]	Externol 65 Gy/6-7 wk	35	80	6	92% 5 yr octuorio!
Eschwege et ol[12]	Externol 60-65 Gy/6-7 wk	64	81	14	46% 5 yr crude
Solmon et ol[43]	Externol 60-65 Gy/6-7 wk	150	65	6	opprox 55% 5 yr crude
Cummings et ol[58]	Externol 45-60 Gy/3-6 wk ond other schedules	57	55	11	61% 5 yr crude

NS = not stoted
Adopted from Leichmon ond Cummings[27]

Table 10. Selected Concurrent Rodiotion: 5 Fluorourocil Schedules

Reference	Chemotheropy	(Gy/froctions)	Primory tumor complete regression		Survivol
			Clinicol	Histologicol	
Byfield et ol[2]	• 5 FU 25 mg/kg/24 hrs IVI D1-5 • Cycle of 5 FU ond rodiotion repeoted opprox D15, D29 etc X3-5	10 Gy/4 D1-4	10/10 (100%)	9.10 (90%)	80% NED 2 yr
Hughes et ol[23]	• 5 FU 300 mg/m2/24 hrs IVI D1-35	45 Gy/25 D1-35 + 10 Gy boost	18/24 (75%)	NS	95% medion follow up 14 mos
Cummings[58]	• 5 FU 1000 mg/m2/24 hrs IVI D1-4 • 5 FU 1000 mg/m2/24 hrs IVI D46-49	24 Gy/12 D1-16 24 Gy/12 D46-62	39/65 (60%)	NEB	64%-5 yr couse specifics

IVI = continuous infusion; IVB = introvenous bolus injection; NEB = no elective biopsy-biopsies of clinicol residuol concer only; NS = not stoted

rate was 94%, and the patient with local recurrence ($T_3N_oM_o$) was retreated with implantation with radioactive Ir^{192} but died of distant metastasis 20 months after the recurrence. Two patients died of intercurrent disease without evidence of cancer, and the rest are alive. All patients developed grades 1-2 (RTOG) side effects with perineal reactions, neutropenia, thrombocytopenia, and gastrointestinal effects. No major complication was reported in the charts.

Discussion

With effective irradiation and chemotherapy regimens, the management of anal cancer has evolved from radical surgery to anal preservation. Some of the recent data using irradiation alone (Table 9), concurrent irradiation and 5 fluorouracil (Table 10) and concurrent irradiation with 5 fluorouracil and mitomycin-C (Table 11) are reviewed.[56] The recent updates of two large series[57,58] show that combination of irradiation with chemotherapy gives a better local control rate and survival rate in tumors more than 2 cms in size. Anorectal function was preserved in 85% to 90% of the patients in whom the local control of the primary tumor was obtained. The major complications that required surgery occurred in 4% to 11% of the patients.

Currently, the intergroup phase III trial (RTOG 8704 and ECOG 1289) has been closed (Fig 1). Arm one uses irradiation with 5 fluorouracil (5 FU) only and arm 2 uses irradiation with 5 FU and mitomycin C. The irradiation is given in a continuous course with a daily dose of 1.8 Gy with a field reduction at 30.6 Gy up to a total dose

Table 11. Selected Concurrent Rodiotion: 5 Fluorourocil-Mitomycin Schedules

Reference	Chemotheropy	Rodiotion	Primory tumor complete regression		Survivol
			Clinicol	Histologicol	
Nigro[33] Nigro et ol[35]	• 5 FU 1000 mg/m2/24 hrs IVI D1-4 MMC 15 mg/m2 IVB D1 • 5 FU 1000 mg/m2/24 hrs IVI D29-32	30 Gy/15 D1-20	97/104 (93%)	83/93 (89%)	5 yr crude 80%
Sischy et ol[47]	• 5 FU 1000 mg/m2/24 hrs IVI D2-5MMC 10/mg/m2 IVB D2 • 5 FU 1000 mg/m2/24 hrs IVI D28-31	40.8 Gy/24 D1-35	NS	57/65 (88%)	3 yr octuoriol 73%
Flom et ol[14]	• 5 FU 100 mg/m2/24 hrs IVI D1-4 MMC 15 mg/M2 IVB D1 • 5 FU 1000 mg/m2/24 hrs IVI D30-34 MMC 15 mg/m2 IVB D30	41-45 Gy/25 D1-35	27/30 (90%)	22/26 (85%)	27 NED 9-76 mos
Sischy[46] Hoghbin et ol[21]	• 5 FU 1000 mg/m2/24 hrs IVI D2-5 MMC 10mg/m2 IVB D2 • 5FU 1000 mg/m2/24 hrs IVI D28-31	45 Gy/25 D1-35 10 Gy/10 opprox D36-45 ±10 Gy implont opprox D73	30/33 (91%)	4/4	4 yr odjusted 77%
Popillon ond Montborbon[37]	• 5 FU 600 mg/m2/24 hrs IVI D1-5 MMC 12 mg/m2 IVB D1	42 Gy/10 D1-16 20 Gy implont opprox D77	57/70 (81%)	NEB	Not stoted
Cummings et ol[6]	• 5 FU 1000 mg/m2/24 hrs IVI D1-4 MMC 10 mg/m2 IVB D1	50 Gy/20 D1-26	15/16 (94%)	NEB	
Cummings et ol[6]	• 5 FU 1000 mg/m2/24 hrs IVI D1-4 MMC 10 mg/m2 IVB D1 • 5 FU 1000 mg/m2/24 hrs IVI D42-45 MMC 10 mg/ mg/m2 IVB D42	25 Gy/10 D1-12 25 Gy/10 D42-54	13/14 (93%)	NEB	5 yr couse-specific 65% 5 yr couse-specific 75%
Cumming et ol[58]	• 5 FU 1000 mg/m2/24 hrs IVI D1-4 MMC 10 mg/m2 IVB D1 • 5 FU 1000 mg/m2/ 24 hrs IVI D46-49 MMC 10 mg/ m2 IVB D46	24 Gy/12 D1-16 24 Gy/12 D46-62	59/69 (88%)	NEB	5 yr couse-specific 76%
Popillon[57]	• 5 FU 600 mg/m2/24 hrs D1-5 MMC 10 mg/ m2 on D1	35 Gy/19 doys 15-20 Gy/implont	80/89 (90%)	NEB	

All time for drug infusions inclusive D1-4 = 96 hours; D1-5 = 120 hours, etc.
IVI = continuous introvenous infusion; IVB = introvenous bolus injection; NEB = no elective biopsy = biopsies of clinicol residuol concer only.
Adopted from Leichmon ond Cummings.[27]

of 45 to 50 Gy. Patients have sequential biopsy after 6 weeks and, if positive, are treated with combination chemotherapy and boost radiation (9 Gy). If the patients have persistent disease at 12 weeks, abdomino-perineal resection is recommended.

The patients in our study are being followed on close follow-up for the local control and for

late side effects. Data from the larger controlled studies should confirm the results of the earlier reported studies.

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The costs of government at all levels have escalated, as have medical costs. We all share the desire to contain these escalating costs. But controlling costs by rationing medical care is not the way to do it.

First, who can live with the consequences of a bureaucracy predetermining life and death choices for us all? The judgement of physicians, patients, and their families intimately knowledgeable of the particulars of a specific case is far more valuable than that of uninvolved, non-physician members of a "think-tank" making blanket decisions in the abstract.

Second, who can live with the arbitrariness of rationing? Who can present to our patients that the reason 7-year-old Coby Howard, of Oregon, must die is that we're only covering 48 bone marrow transplants and he is #49? Not that he's a poor candidate. Not that the technology is unavailable. Just that after 48 cases, medicine in his state becomes "two-tiered": If you're rich, you can buy it, if you're not, you die.

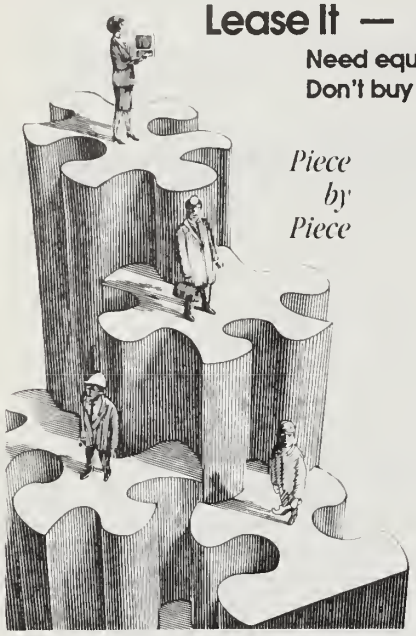
Finally, it is fallacious to believe there are *obvious,* "high tech," low survivability procedures which can form the nidus of a list of restricted procedures. Not that many years ago, the heart transplant would have fallen into this category, as would have attempts to maintain the lives of 1500 gram . . . or even 1000 gram babies. Had these once extraordinary measures been rationed into limited use yesterday, they could not become reasonable risks today, and even "ordinary" tomorrow. Lives would not have been saved. Who is to say which of the highest cost, highest risk procedures of today will be "ordinary," lifesaving techniques of tomorrow?

Some degree of rationing occurs on a daily basis in medicine. I would like to think this is done with sensitivity and the special insight that an individual and his family has with his physicians. These decisions are best made by the individuals involved and their physicians. Each case is inevitably more complex than it seems in the abstract. Each case has heart-wrenching, mitigating factors, best decided by individuals closely involved, not *pre*determined by government drawn, cost containment charts.

Not only does rationing risk providing the best care for individuals, but also, it risks the very progression of medicine. What really distinguished Science in the Dark Ages was its lack of progression due to the rigid attitude that to be acceptable, an idea must be "established."

We've got to find another way to contain costs, because the American way is to *push* the envelope, not just throw up our arms and give up, leaving countless loved ones in the lurch.

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AUXILIARY — *Subsidiary: supplementary; additional. A group or organization that assists or is supplementary to a larger one; a women's auxiliary.*

ALLIANCE — *Any union, relationship, or connection by kinship, marriage, common interest, or the like.*

(Webster's Unabridged Dictionary)

What began as an organization devoted to entertaining the wives of physicians while their husbands attended medical conventions, now mobilizes support for legislation, leads the fight against family violence, and breaks record after record raising funds for medical education. What began as an organization dedicated to promoting "acquaintances" among doctors' families, now is an advocate for medical family well-being with programs of education, prevention, and support. What began as a "for women only" organization, now seeks the active involvement of the spouses of the growing number of female physicians.

AMA AUXILIARY ACTION — During the 1992 AMAA Annual Session, an open forum was held during which AMAA members discussed the pros and cons of a proposed name change. By an overwhelming majority, the AMAA members elected to change the name of the AMERICAN MEDICAL ASSOCIATION AUXILIARY to the AMERICAN MEDICAL ASSOCIATION **ALLIANCE.**

AUXILIARY to the KENTUCKY MEDICAL ASSOCIATION — During the 1992 AKMA Fall Board meeting, the membership and planning committees met and discussed the possibility of the state organization changing its name from AUXILIARY to ALLIANCE. The Board supported this concept and at the recent Annual meeting of the Auxiliary to the Kentucky Medical Association, the delegates unanimously approved the Board's recommendation.

Members of the Auxiliary felt a need to update the profile of our organization to reflect its close collaborative working relationships

"Members of the Auxiliary felt a need to update the profile of our organization to reflect its close collaborative working relationships with medical associations."

with medical associations. Our members work side by side with physicians and organized medicine to better understand the issues and formulate appropriate strategy.

Our name change is designed to communicate:

- partnership with the Kentucky Medical Association
- concern about quality medical care
- legislative action/involvement
- the diversity of male/female membership (physician spouses)
- community health promotion
- professionalism
- concerns for medical family
- concern for the welfare of the community and other people
- continued involvement in community programs

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In addition, we hope to emphasize by this name change that the state organization is *not* primarily social in nature; that its membership are *not* all women; *not* all homemakers; *not* all affluent; and that the organization is *not* self serving.

We encourage all physician spouses to become actively involved in this new Alliance. For membership information, please contact:

Jean Wayne, Executive Secretary
Kentucky Medical Association
Alliance
301 N Hurstbourne Parkway, Ste 200
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502/426-6200

Gloria Griffin
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Primary Thrombosis in the Upper Extremity

TO THE EDITOR: Primary, spontaneous, or "effort" thrombosis of the axillary and subclavian veins is a complex and difficult problem to manage. Sometimes referred to as Paget-Schroetter syndrome, its occurrence is not uncommon in healthy, active, muscular, young patients presenting with significant, disabling, upper extremity swelling and pain. The gravity of the situation further escalates by the unexpected, relatively sudden onset of symptoms and the long-term morbidity of this disease. The importance of early recognition and treatment of this disease in preventing acute complications and long-term morbidity was recently emphasized in the February 1993 issue of the *Journal of the Kentucky Medical Association*.[1] The purpose of my editorial is to update your readers about data regarding the diagnosis and treatment of primary thrombosis of the axillary and subclavian veins.[2-4]

The diagnosis of upper extremity vein thrombosis can be made with high accuracy by using duplex scanning and upper extremity air plethysmography. The addition of color-coding to duplex scanning has greatly enhanced the ability to accurately identify thrombosis of the axillary and subclavian veins.[2] Similar to the lower extremity, determination of maximum venous outflow of the upper extremity with air plethysmography is a highly accurate means of identifying axillary and subclavian vein thrombosis.[3] However, venography still is believed to be essential if thrombolytic therapy is used.

The goal of treating axillary and subclavian vein thrombosis should be to restore patency of the veins. In a recent study by Machleder[4] of 50 consecutive patients with primary axillary and subclavian vein thrombosis, the best long-term success for relief of symptoms was achieved in those patients who were treated with thrombolysis that resulted in a patent axillary and subclavian vein. At final evaluation (mean follow-up, 2 years), 93% of the patients with a patent axillary and subclavian vein were symptom-free, compared with 64% of those who had occluded veins. Intravenous urokinase was the most effective thrombolytic agent. Urokinase therapy was started a mean of 10 days after the onset of the patients' symptoms and the only complication that occurred was axillary hematoma. Seventy-seven percent of the patients treated with urokinase had patency established, compared with 36% treated with streptokinase and 25% with heparin. In addition, patients who had residual mechanical compression of the subclavian and axillary veins by venogram after thrombolysis underwent 3 months of anticoagulation followed by first rib resection. No re-thrombosis of the vein occurred and 86% of the patients were symptom-free.

Primary thrombosis of the axillary and subclavian veins remains a challenging clinical problem. Recent studies suggest that the diagnosis can be made with duplex scanning and upper extremity plethysmography. Thrombolysis has resulted in the reestablishment of patent axillary and subclavian veins and 93% of patients are symptom-free after 2 years.

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Preventive Medicine

TO THE EDITOR: The article "Preventive Medicine: What do future practitioners really need? Are they getting it in Medical School?" by B. Phillips, et al, *KMA Journal*, Vol 91, March 1993, was stimulating.

The idea of "preventive medicine" as represented in the medical literature has broadened recently. The issue of alterations of behavior patterns which can pose a risk to health has emerged as an issue over and above specific "disease prevention categories."

If "preventive medicine" encompasses the whole area of living wisely, then, strictly speaking, we are outside the bounds of the Hippocratic corpus. Then, within these larger bounds, a most important text is the *Bible*. I wonder how many of these students have read the book of Proverbs? I use the expression "outside the bounds" with a certain irony; Hippocrates, as a priest of Aesculapius, would not have considered as possible the existence of science without a moral foundation.

Consideration of issues of longevity in a population cannot be done in a vacuum. Prolonging the life expectancy substantially, as has been

done in the last 25 years in this country, can lead to severe social stresses as the impending bankruptcy of our social security system, Medicare system, and indeed our federal government can attest. For instance, if smoking were totally banned in this country and if such a ban could be enforced, the resulting prolongation of life expectancy of as much as a third of the population of this country by another 6½ years would be a substantial stress.

Consideration of the genetic endowment of the individual from his parents as well as the effect of the behavior of the individual on the community around him are useful in predicting health problems in individuals. I believe that the development of a comprehensive medical records system allowing the maintenance of long term records about patients, their behavior, the behavior and illnesses of their genetic relations, as well as the behavior and illnesses of their immediate community will be useful in this regard.

F. Andrew Morfesis, MD
Grays Knob, KY 40829

Certification for Dietitians and Nutritionists

TO THE EDITOR: Current Kentucky law mandates certification for nutrition professionals who use the titles dietitian, registered dietitian or certified nutritionist. KRS Chapter 310 also makes it possible for the State to prosecute anyone using the legally protected titles without certification.

What this means to physicians is that the law provides a legal definition of the above mentioned titles and therefore assurance that persons using these titles have successfully completed academic and experience requirements. Likewise the law assures that certified nutritionists are registered dietitians and/or have completed at least 12 hours of graduate study in nutrition. State licensed facilities and facilities inspected by the State have been advised that their employees who hold themselves out as dietitians or certified nutritionists must be certified. The law applies in like manner to dietitians and certified nutritionists in private practice.

The certification law does not prohibit any other licensed professional from carrying out any therapy or practice for which he is duly licensed, including physicians, osteopaths, podiatrists, chiropractors, dentists and nurses.

It should also be noted that the certification law for dietitians and nutritionists does not affect persons who own health food stores or distribute or sell dietary supplements nor does it apply to other persons who provide dietary advice so long as they do not use the titles dietitian, registered dietitian, or certified nutritionist.

For additional information please contact the State Board of Certification for Dietitians and Nutritionists, Division of Occupations and Professions, 700 Louisville Road, PO Box 456, Frankfort, KY 40602-0456. Please call 502/564-3296.

David L. Nicholas, Director
Division of Occupations and Professions

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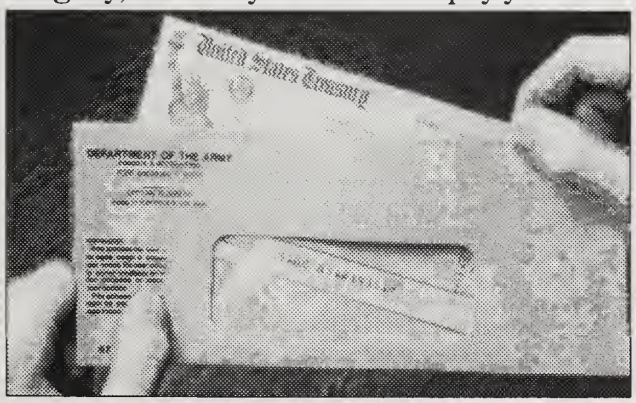
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Taylor Drug #21
Wal-Mart Pharmacy
Whitesville Drug Store

Edmansan
Prescriptian Shap

Fayette
Hi-Acres Phormocy
Hubbard & Curry Phormocy
Hutchinson Drug
K-Mort Phormocy
All Kroger Phormocies
Professianol Arts Apothecory
Randall's Phormocy
Toylor Drugs
The Medicine Shappe
Worehouse Drugs
Woodhill Pharmacy

Fleming
Plaza Pharmacy

Flayd
Archer Clinic Pharmacy
Betsy Loyne Phormocy
Brooks Pharmacy, Inc
Mud Creek Clinic Phormocy
Our Lody Of The Woy Hospitol

Franklin
East Side Pharmacy
Fitzgerald Drugs
K-Mort Phormocy
Kroger Pharmacy
Medicine Shoppe
Reliable Drugs
Toylor Drugs
The Prescription Center

Fultan
City Super Drug
Evons Drug Compony
Rumfelt Drug
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Sutton Phormocy

Grant
Gront County Drugs

Graves
K-Mort Phormocy
Stones Drugs
SuperX Drugs
Wilson Rexoll Drugs

Graysan
Clorkson Drug Store
Reliable Drugs

Green
Madel Drug Stare

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Stultz Pharmacy

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Krager Compony
Lincaln Troil Phormocy
Radcliff Drugs
Shawers & Hays Drugs
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Family Drugs
Madisanville Pharmacy
Natian's Medicines
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Reliable Drugs
SuperX Drugs

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Annville Pharmacy
Clinic Pharmacy

Jeffersan
Alliant Health System Pharmacy
Applied Pharmacy Therapeutics
Art Jacab Prescriptian Shoppe
Band Pharmacy
Calanial Drugs
Cax's Pharmacy
Cox's Pharmacy #1
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Harding Pharmacy
Haldaway Drugs
Hume Pharmacy
K-Mort Pharmacy
Kaby Drug Campany
All Krager Pharmacies
Ook Drug Campony, #1
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Rauben's Pharmacy
St. Denis All Core
All SuperX Drugs
All Taylar Drugs
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Unian Prescription Center
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Worehouse Drugs

Jessamine
Drug Mart
Medicine Shappe
Toylar Drugs

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Katterjahn Drug Stare
Krager
SuperX Drugs
The Medicine Shappe

McCreary
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Mercer
Kroger Campany
SuperX Drugs
The Medicine Shoppe

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Metcalfe Drugs
Nunn Drugs

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Calica & Whitt Drug
Emil W. Baker, Pharmacist
Rass Drugs
SuperX Drugs

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Reliable Drugs

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Krager Campany
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Todd
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A Ship Without A Name

T. Rothrock Miller, MD

Vantage Press, Inc
516 West 34th Street
New York, NY 10001
1992
$17.95 (Hard cover)

This personal reflection and historical piece makes for interesting and educational reading. Dr Miller, having practiced and retired in Lexington, Kentucky, tells us a tale of his World War II experience aboard a patrol craft designed for escort and rescue operations. On board "M.A.S.H." type hospital setup permitted some medical attention for the wounded and dying. This book is full of detail, sprinkled with actual photographs and biographies. From Okinawa to China, the USS *PCE (R)855,* as the ship was known, endured combat and tragedy, but fulfilled its mission.

Actual copies of the ship's log, sometimes in crude form, its "War Diary," and other historical data from the National Archives, Department of the Navy, and from the Navy Historical Section (Operational Archives) assured the validity of Dr Miller's descriptions. As the medical officer, he could detach himself from the running of the war, and remember the life otherwise. His shipmates added their memories, and their heroism was remarkable. Too quickly you reach the Epilogue, where time has taken some of the actors, but has aged well the others. The names and histories get to be familiar by book's end, with the gentle and very human telling by Dr Miller.

Doctors and the Law: Defendants and Expert Witnesses

Hon. Hiller B. Zobel and Stephen N. Rous, MD

March 22, 1993
224 pp, $22.95
ISBN 0-393-03450-X

This short and concise book distills the legal mixture quite well. Whether as a defendant or expert, the physician should be knowledgeable of the playing field and ready to participate in the major leagues. With a comfortable writing style and lots of verbal hugging, the authors take a parental approach to these lessons. Reading through the chapters reminds me of a basic science book, constructed for the naive, but with respect to their feelings. Legal fencing hurts at times, despite covering our bodies with protection. Each thrust attempts to score points, with the tabulation being loss of ego, finances, and peer respect. Somehow with this book you will feel ready, though still anxious, when you are on the firing line.

Part One is titled "THE DOCTOR AS DEFENDANT." Each chapter opens with terms such as "You and Your Lawyer," "A Suit Is Not a Shroud," and "Into the Arena: The Bull's View." Each part of the legal method is dissected, from the laying on of the papers to the terminal appeals. Many suggestions and downright commands spot these sections, as if we sometimes weren't listening. Although I am critical of such a didactic approach, the schoolroom milieu may be the least obnoxious for this teaching. Since so many of us will face this malady, a lawsuit now becomes palatable, because we have the utensils to deal with it.

"THE DOCTOR AS WITNESS" introduces Part Two. Here the combatants change, but remember that we are still on the lawyers' home field and they have the advantage. Even if the opportunity or the obligation never presents itself, these chapters are filled with information for the physician as a defendant or expert. Helping your lawyer with constructing a defense often necessitates finding testimony, shaping ideas, practicing for the drama, and arming oneself for the opponent's shots. Sometimes you act as the teacher to the jury, other times as the colleague, and then as the gladiator. Each role has direction in these subsequent chapters.

Finally there are the times when you are consulted, but not officially brought into the matter. Such conferences with lawyers can stop a malpractice action, if there is insufficient cause. Likewise, if the evidence is overwhelmingly indicting, an appropriate settlement can be developed. This work might entail reading depositions, reviewing the literature, or just talking about the practice of medicine in your special field of interest.

This book is really a primer. The writing is terse, but friendly. Information in some parts bombards the reader, but a nice index and introductory material make recall easy. The price is right and the help is there.

Stephen Z. Smith, MD
Book Review Editor

1993

JULY

15-17 — First Annual Mid-South Symposium on Cardiovascular Disease; The Laurence A. Grossman Medical Learning Center, St Thomas Hospital, Nashville, TN. Contact: Registration Secretary, Extramural Programs Dept, American College of Cardiology, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; 800/257-4739 (outside the US and Canada, 301/897-2695); FAX 301/897-9745.

SEPTEMBER

11-14 — The Decade of the Brain: An International Conference; The Omni-Shoreham, Washington, DC. CME — 28 Credit Hours, AMA Category 1. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037, 202/994-4285 (phone), 202/994-1791 (fax).

18 — Tenth Annual Ophthalmology Seminar: Update on Management of Age-Related Macular Degeneration; Humana Hospital Audubon, Louisville, KY. Contact: Cathy Edens, 240 Audubon Medical Plaza, Louisville, KY 40217; 502/636-2823.

OCTOBER

1-3 — International Liver Symposium: Marriott Crystal Gateway Hotel, Arlington, VA. Contact: Daniel E. Reichard, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037, 202/994-4285 (phone), 202/994-1791 (fax).

13-17 — The American Society of Internal Medicine 37th Annual Meeting; J. W. Marriott Hotel, Washington DC. Contact: Melinda Klein; 202/835-2746, ext 266.

31-Nov 5 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

NOVEMBER

14-18 — 97th Annual Meeting of the American Academy of Ophthalmology; McCormick Place, Chicago. Contact: The American Academy of Ophthalmology, Meetings Department, PO Box 7424, San Francisco, CA 94120-7424; 415/561-8500.

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KMA Board of Trustees Spring Meeting

The Board spent considerable time discussing Governor Brereton Jones' plan for health care reform, and the anticipated Special Session of the Kentucky General Assembly.

The KMA Board of Trustees held its two-day Spring meeting on April 14 and 15, 1993, at the Hyatt Regency Hotel in Louisville. The Board members heard reports from the President, the Secretary-Treasurer, the Auxiliary President, the Senior Delegate to AMA, the Vice Dean of the University of Louisville School of Medicine, the Chairman of the KMIC Board of Directors, the President of the Board of Medical Licensure, and the Commissioner of the Bureau for Health Services.

The Board approved the expenditure of $2,600 for the Subcommittee on Domestic Violence to develop packets of information on domestic abuse, and adopted a budget for the 1993-94 Association year. Nominees were selected for the KMIC Board of Directors, as well as for the service on Governor-appointed councils. The Board members approved draft regulations submitted by the Board of Medical Licensure which would require mandatory continuing medical education as a condition of licensure. Legal cases of interest to KMA were discussed, and the reports of the Membership Committee and the Ad Hoc Committee on the KMA/KMIC Headquarters Location were accepted.

Comprehensive reports were given concerning the activities of the Committees on National and State Legislative Activities. The Board spent considerable time discussing Governor Brereton Jones' plan for health care reform, and the anticipated Special Session of the Kentucky General Assembly. The Board members also finalized recommendations for current KMA policy and strategy in regard to health care reform.

The next regular meeting of the Board was scheduled for August 5-6, 1992.

PEOPLE

In June 1991, the University of Kentucky Medical Alumni Association Board established the Distinguished Alumnus, Alumni Service, and Honorary Alumnus Awards in recognition of distinguished persons associated with the UK College of Medicine. Several KMA members were included when the first awards were given in 1991-92, and again this year when the 1992-93 recipients were named. The members, their awards, and Alumni Board profiles are shown below.

Alumni Service Award — *A graduate of the UK college of Medicine or a former resident at the Medical Center who has performed volunteer actions and/or services that greatly advanced the goals of the College or the profession.*

Ardis D. Hoven, MD ('70)
Alumni Service Award, 1992-93

Dr Ardis Hoven, a native of Columbus, Indiana, is an infectious diseases specialist associated with the Lexington Clinic in Lexington. She became a member of the American Board of Internal Medicine in 1973 and was named a Diplomate of the Infectious Disease Subspecialty Board in 1975. She was an assistant clinical professor of medicine/infectious diseases at the University of Kentucky College of Medicine from 1975 to 1983. She presently serves as hospital epidemiologist at both St. Joseph's Hospital and Humana Hospital, Lexington and is an active staff member at St. Joseph's.

Dr Hoven is President-Elect (1992-93) of the Kentucky Medical Association (KMA); chair of the Fayette County Board of Health; alternate delegate for Kentucky to the American Medical Association; a member of the advisory committee on group practice of AMA, and a member of the Executive Committee of the Fayette County Medical Society. When her term of office begins, she will be the first woman to serve as President in KMA history. She serves as a member of the Dean's Advisory Committee of the UK College of Medicine and as a trustee of Kentucky Christian College.

In 1991, she received the Educational Achievement Award for Outstanding Contribution in the Field of Medicine from the Kentucky Medical Association. She is a member of Alpha Omega Alpha.

The Board of the UK Medical Alumni Association recognizes Dr Hoven's service to her College and profession in making this award.

Honorary Alumnus Awards — *An individual who is not an alumnus but who has present or prior association with the College and who has performed dedicated and distinguished service which has made him or her a notable and important part of the College. This award may be given posthumously.*

Andrew M. Moore, MD
1918-1989

A native of St. Louis, MO, Dr Moore came to Lexington in 1952 to begin his practice in plastic and reconstructive surgery with the surgical group of Drs Dorton, Webb and Royalty. He was the only plastic surgeon in Fayette County until 1965. Dr Moore served several professional organizations in almost every capacity including president of the American Association of Plastic and Reconstructive Surgery, president and chair of the Board of Trustees of the American Association of Plastic Surgeons, and president of the Southeastern Society of Plastic and Reconstructive Surgeons. Dr Moore was instrumental in establishing the division of plastic surgery at the UK College of Medicine and helped recruit the first chair of the department of surgery.

Mary Workman

"She served as a mother figure to all medical students during a very tough and tedious medical school curriculum." So said the alumnus who nominated Mary Workman to receive the Honorary Alumnus Award. Mrs Workman served as staff assistant in the College's Office of Education from June 1977 to February 1989. While her official job description detailed many duties involving registration and student activities, alumni from that era remember her as a willing listener and the person they could always turn to for encouragement. She was named an honorary class member by every graduating class from 1978 through 1990. She is currently an administrative staff assistant for the UK Hospital's department of operating room services.

Hiram Polk, Jr, Department of Surgery, University of Louisville, was recently named president-elect of the Southeastern Surgical Congress.

UPDATES

Best Day for Breast Cancer Surgery

U of L reports that a surgery professor believes he may have found a link between the timing of breast-cancer surgery and its success.

Surgical oncologist **John S. Spratt, MD,** studied the cases of 40 local women whose cancer was

detected in a national study in the 1970s.

His research showed a profound contrast in the survival rate of women whose breast-cancer surgery was performed in the middle of their menstrual cycles compared with those who had surgery during or near their menstrual periods.

Dr Spratt found the 10-year survival rate was much greater for those women whose breast-cancer surgeries occurred from the seventh to 20th day of the menstrual cycle.

Also, his research showed that cancer was much more likely to recur in women who had surgery at other times.

Dr Spratt's study adds to the body of evidence from several other researchers that generally identifies which 2-week half of the menstrual cycle appears to be best for breast-cancer surgery.

The U of L study is unique because it has the potential for expansion into a national study that could pinpoint the optimum day in a menstrual cycle for breast cancer surgery.

Dr Spratt said it would be possible to do an expanded study because detailed records were kept as part of the national breast cancer detection project that began in 1972.

Through that research project a total of 1,087 new cases of cancer were recorded at hospitals in 29 locations, including Louisville.

Dr Spratt said assembling and updating those records would provide a large enough database to accurately determine the day where surgery is most likely to succeed. He said this would be possible because the cancer-detection project recorded the date of each woman's most recent menstrual period before surgery — a fact not always kept in medical records.

Dr Spratt has proposed his idea for the national study to the National Cancer Institute. He believes the study could be completed in a year if national agencies provided support staff to update existing data by finding and interviewing patients.

If the NCI decides to proceed, Dr Spratt hopes to help conduct the study.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Bourbon

Roberta L. Allison, MD — FP
2017 S Main, Paris 40361
1986, U of Texas

Fayette

Khalid Chowdhury, MD — OTO
740 S Limestone B363, Lexington 40536
1982, U of Saskatchewan

John R. Langefeld, MD — FP
3174 Custer Dr, Lexington 40517
1982, U of Louisville

Harry Lockstadt, MD — ORS
120 N Eagle Creek #521, Lexington 40509
1980, U of Western Ontario

John D. McBrayer, MD — C
1800 S Limestone #401, Lexington 40503
1978, U of Mississippi

M. Clive Robinson, MD — TS
UKMC, CT Surgery NM273, Lexington 40536
1970, U of Otaga, New Zealand

Hickman

Edward P. Isaacs, DO — FP
PO Box 157, Clinton 42031
1987, WV School of Osteo Medicine

Jefferson

William J. Durkan, MD — AN
1828 Deckard School Rd, Radcliff 40160
1983, Thomas Jefferson Medical Col

Ana E. Dvoredsky, MD — P
2827 Woods Club Rd, Louisville 40241
1972, U of Chile

Carol A. Hansen, MD — AN
483 Mallard Creek Rd, Louisville 40207
1988, U of Kentucky

Sanford L. Lapin, MD — AN
5616 Timber Creek Ct, Prospect 40059
1986, Rush Medical Col

Resad Pasic, MD — OBG
9895 Timberwood Cir, Louisville 40223
1975, U of Sarajevo

Rosalyn G. Sarmiento, MD — PD
10 Highwood Dr, Louisville 40206
1989, Medical Col of Alabama

Bhanu A. Thaker, MD — FP
6703 Outer Loop, Louisville 40228
1969, SMT, NHL, Municipal Med Col of India

David L. Winsch, PHD
332 W Broadway, Louisville 40202

Pulaski

Keith G. Sinclair, MD — S
340 Bogle St, Somerset 42501
1982, Middlesex Hosp Med Sch, London

In-Training

Jefferson

Mehmet S. Akaydin, Jr, MD — P
Wagar C. Aziz, MD — ORS
Melody A. Burton, MD — PD
George C. Charonis, MD — OPH
Thomas V. Connely, MD — S
Debra Jo Eadens, MD — IM
Philip F. Fisher, MD — PMR
Shawn D. Glisson, MD — IM
Scott A. Haas, MD — P
James I. Harring, MD — IM
Peter K. Henke, MD — S
Sandra Kay Hensley, MD — PD
Marie A. Herrmann, MD — PTH
Pamela G. Kantorowski, MD — OBG
Frederick J. Klein, MD — EM
Jagdish N. Kothari, MD — IM

John M. McKinney, Jr, MD	**— S**
Corrie A. Naasz, MD	**— PD**
Bhanu Pant, MD	**— N**
Paul J. Sims, MD	**— PTH**
Griffith C. Steiner, MD	**— OPH**
Celestino Vega, MD	**— FP**
Charles L. Waller, MD	**— DP**

DEATHS

Charles L. Kirkpatrick, MD
Atlanta, GA
1903-1992

Charles L. Kirkpatrick, MD, a retired internist, died November 26, 1992. Dr Kirkpatrick graduated from Vanderbilt University School of Medicine in 1930 and was a life member of KMA.

Boyce E. Jones, MD
London
1911-1993

Boyce E. Jones, MD, a retired pulmonary disease specialist, died March 21, 1993. A 1943 graduate of the University of Louisville School of Medicine, Dr Jones was a life member of KMA.

James K. Hurlocker, MD
Harlan
1931-1993

James K. Hurlocker, MD, an obstetrician-gynecologist, died March 22, 1993. Dr Hurlocker graduated from the University of Tennessee College of Medicine in 1956 and was an active member of KMA.

Caroline P. Scott, MD
Lexington
1901-1993

Caroline P. Scott, MD, a retired pediatrician, died March 25, 1993. A 1933 graduate of the University of Pennsylvania School of Medicine, Dr Scott was a life member of KMA.

Leighton L. Cull, MD
Lexington
1903-1993

Leighton L. Cull, MD, a retired surgeon, died April 13, 1993. Dr Cull was a 1928 graduate of the University of Louisville School of Medicine and a life member of KMA.

C. Noel Hall, MD
Versailles
1915-1993

C. Noel Hall, MD, a retired general practitioner, died April 27, 1993. A 1941 graduate of the University of Louisville School of Medicine, Dr Hall was a life member of KMA.



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Louisville, KY 40222-8512

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Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was *not* significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter²). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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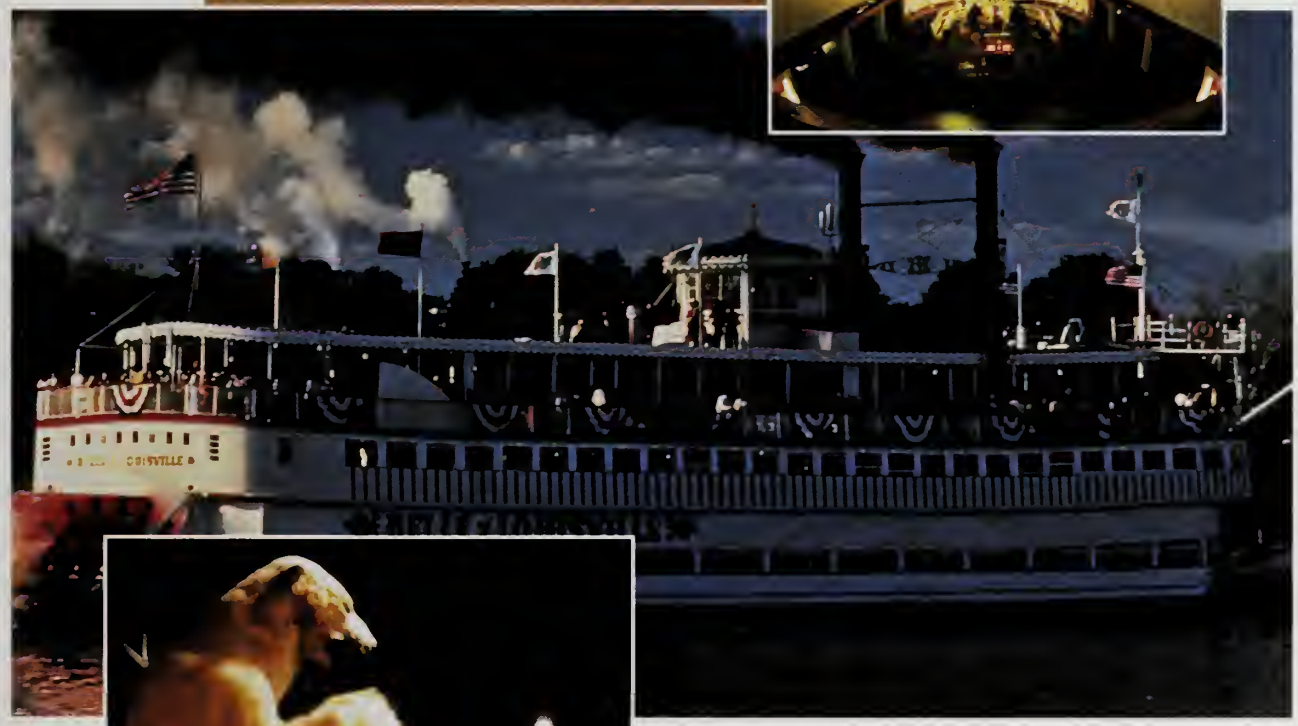
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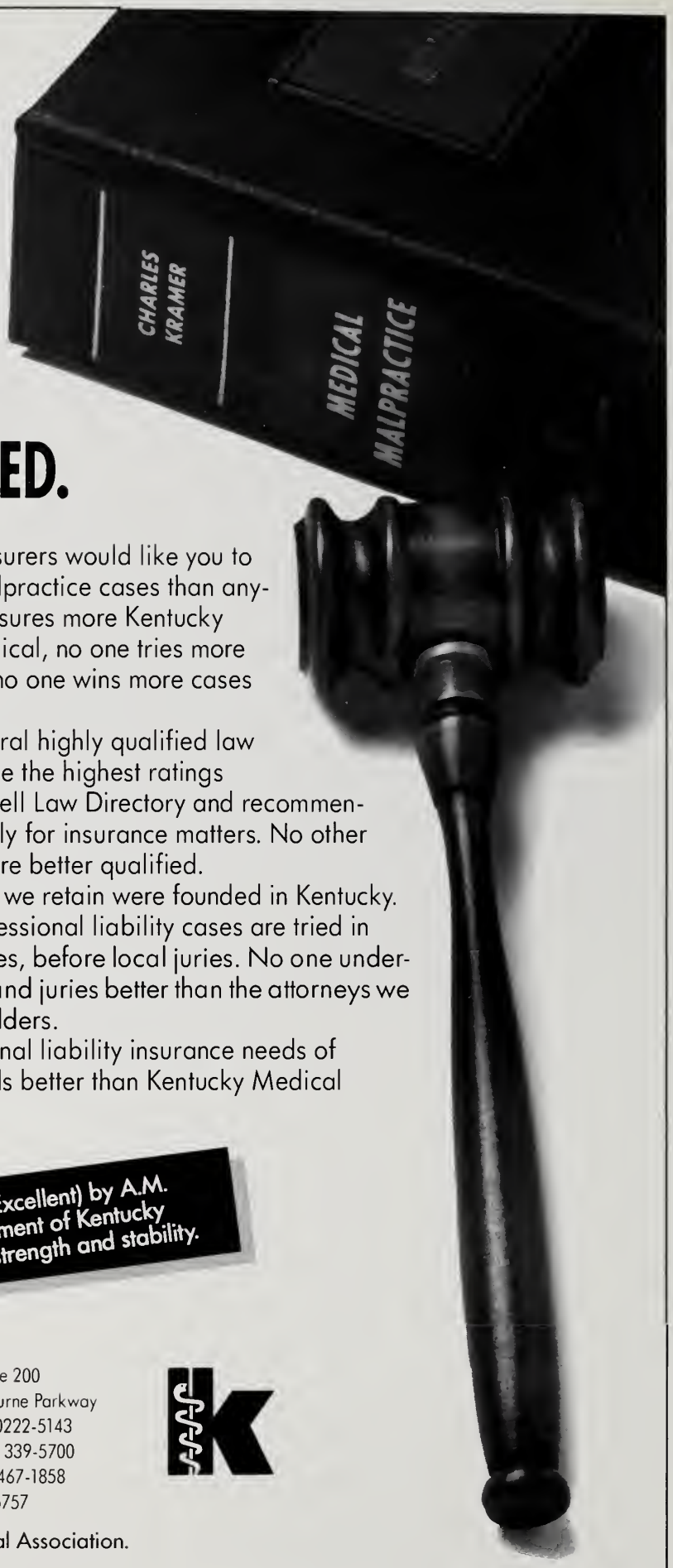






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COVER: Discover the sites of Louisville, host of this year's KMA Annual Meeting. Those pictured on the cover are, clockwise, the historic Churchill Downs, home of the Kentucky Derby and 1994 home of the Breeders Cup; Kentucky Derby Museum, which recaptures the excitement of past Kentucky Derbys; Belle of Louisville, which offers river cruises along the Ohio River; and the Museum of History and Science/IMAX Theatre — an exciting collection of science and learning exhibits and demonstrations housed in a 19th century warehouse.
This issue contains a short, informative article on this progressive city and how it will enhance your attendance at the Annual Meeting. *See page 301.*

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William B. Monnig, MD

THE Topic of Interest

Health care and its reform remains a topic of interest at the state and federal levels. As I write this article, it is mid June 1993. The first Extraordinary Session of the State Legislature has ended with the passage of House Bill 1 that establishes a provider tax on various health care entities, including physicians who practice in Kentucky. Our selective tax is 2% of gross revenues and cannot be increased without specific action of the General Assembly. However, it is also stated that the tax cannot be passed through to the patients who receive the care or to the insurers.

The KMA has not and will not be supportive of a selective tax on physicians to provide medical care to an indigent population that society has chosen to take responsibility for their health. The state government has thus far rejected our arguments that the state's ability to legally extract three dollars from the federal government treasury for every dollar that the state raises for Medicaid is not sufficient reason to raise the state's share by selectively taxing physicians. The KMA leadership has initiated inquiries into the constitutionality and legality of this non-pass-through selective tax. As this article is being written, it is too early to state what avenues can and should be pursued.

Regardless of the immediate results of this tax, it is obvious that this funding mechanism will not be sustained by the federal government. President Clinton's economic package includes $11 billion in cuts to the Medicaid program, and more than $54 billion in cuts to the Medicare program. There will be intense national pressures to eliminate the federal matching program to poor states like Kentucky.

"The KMA has not and will not be supportive of a selective tax on physicians to provide medical care to an indigent population that society has chosen to take responsibility for their health."

"The development of data bases on cost and quality of health care, the collection of the data, analysis of the data, and conversion of the data into useful information is a great place to initiate a cooperative atmosphere and build confidence in health care reform efforts."

Is it another cruel joke for the state government to use the ruse that the provider tax will be used to achieve equitable reimbursement for physician services in the Medicaid program? Will the new Legislative Task Force see the improbability of sustained federal matching funds, and will they advocate other funding mechanisms to sustain needed care for the indigent? Does state government see its obligation to provide reasonable reimbursement for health services rendered to the

Medicaid population? We will see if the Legislative Task Force can adequately address these issues. Adequate financing of health care reform is the one area that is the most difficult area for governments to address, since it requires either raising revenues through increased taxes or reallocating existing revenues. It is difficult to maintain public confidence if the government continually demands higher taxes. That fact is a good reason for state government to approach universal health care cautiously and incrementally. It is also a good reason to keep most health care insurance coverage a private prerogative.

"There seems to be an undercurrent of anxiety that dictates that a quick fix to health care costs is necessary, and rate setting has surfaced as the answer."

If the state government believes it has an obligation to provide high-quality, cost effective health care, and also has the expertise to create such a health care system, it already has assumed the responsibility for providing such care to a large segment of our population, ie, the Medicaid eligible, the state employees, the prisoners. No additional laws are needed to implement meaningful health care reform for these populations. If the state government can address the problems of these groups, there will be more confidence that government intervention in the private sector and the uninsured sector is warranted.

It is reasonable for government to establish legitimate data bases about the cost and quality of health care to facilitate the public's decision making about purchasing health care.

There is a misconception on the part of many legislators that this is an easy task. It will soon become obvious that even this task is expensive, based on inexact science, time consuming, and of unproven benefit. It is a task which requires a cooperative effort by consumers, payors, providers, and the government. The development of data bases on cost and quality of health care, the collection of the data, analysis of the data, and conversion of the data into useful information is a great place to initiate a cooperative atmosphere and build confidence in health care reform efforts.

There is an inimical interest in governments' direct involvement in cost control through rate and fee regulation. Historical perspectives are largely being ignored as this issue is being discussed. There seems to be an undercurrent of anxiety that dictates that a quick fix to health care costs is necessary, and rate setting has surfaced as the answer. Hopefully the new Task Force will take the time to study the RBRVS and volume performance standards that are being used by Medicare. This system has been implemented nationwide and is fraught with many unforeseen problems. The relative values of services are still being adjusted. Frequently, rural areas have lower reimbursement. The allowable increase in the volume performance standard for surgical services was higher than that for nonsurgical services, further aggravating the disparity between procedure reimbursement and cognitive skill reimbursement. The calculated increases in the volume performance standards that will be mandated by the Congress will exceed general inflation and/or the increases in the Domestic Price Index.

"The good news is that while all the rhetoric is taking place, physician fee increases have gradually and steadily decreased until they are approaching the CPI. In 1992, the increases were 5.9%."

There is no better-designed method of physician fee regulation. If the Legislative Task Force recommends physician fee regulation, there is no reason to believe that their system will be better than RBRVS and VPS, and those systems are not controlling health care costs.

The good news is that while all of the rhetoric is taking place, physician fee increases have gradually and steadily decreased until they are approaching the CPI. IN 1992, the increases were 5.9%.

The members of the KMA have an opportunity to talk to our state legislators. We need to keep them informed of the facts about health care cost and quality. The legislators want to do the right thing, but they certainly have been influenced by the high cost of health care and must be made aware of the facts. We will continue to support your efforts.

William B. Monnig, MD
KMA President

The Prevalence of Congenital Cervical Spinal Stenosis in 262 College and High School Football Players

Mark G. Smith, MD; Mark Fulcher, MD; Joel Shanklin, MD; Edward D. Tillett, MD

Pavlov's ratio is a commonly utilized method for evaluating athletes for cervical stenosis. We evaluated the lateral cervical spine film and determined Pavlov's ratio for 262 college and high school football players. Twenty (7.6%) of these athletes had radiographic evidence of congenital cervical stenosis according to this method. The condition may be more common than expected.

Congenital or developmental cervical spinal stenosis is a narrowing of the spinal canal in its sagittal (Anterior-Posterior) diameter. When combined with a hyperextension or hyperflexion injury to the neck, this condition predisposes the player to a neurapraxia of the spinal cord. Torg reported the largest series of athletes who had experienced an episode of neurapraxia secondary to contact sports. Seventeen of these 32 occurrences could be attributed to developmental cervical stenosis alone, while the rest had an associated component of acquired spinal stenosis from ligamentous instability, intervertebral disc disease and congenital cervical anomalies. Congenital stenosis alone has not been shown to predispose the athlete to permanent neurologic injury.[3]

According to Torg, the best prediction of cervical spinal stenosis is the spinal canal:vertebral body ratio which is called Pavlov's ratio.[3, 4] The ratio is measured on a lateral cervical spine röentgenogram at the C-4 level as depicted in Figure 1. Until recently, the measurement of only the sagittal diameter of the spinal canal was used in assessing the patient for cervical spinal stenosis. A

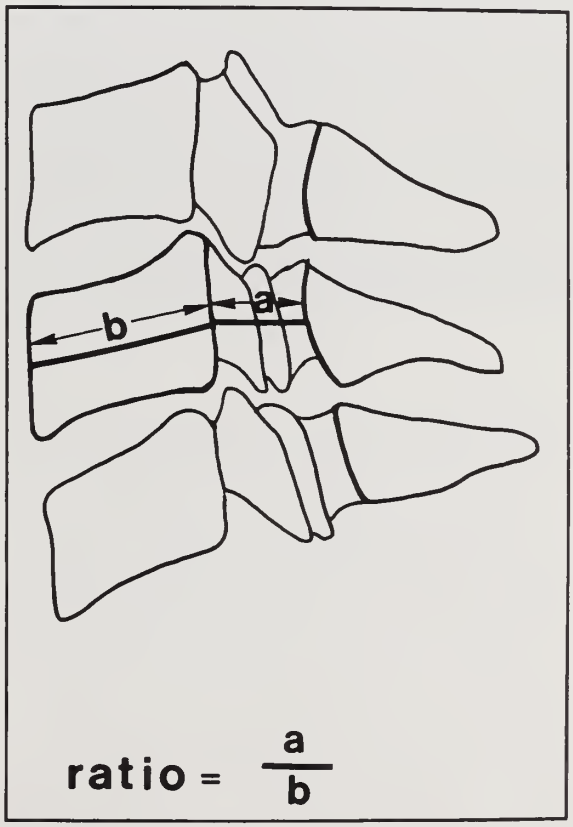


Fig 1 — The sagittal diameter of the spinal canal is measured from the posterior surface of the vertebral body to the nearest point of the corresponding spinal laminar line, distance (a). The sagittal diameter of the vertebral body is measured at the midpoint from the anterior to posterior surfaces, distance (b). The spinal canal:vertebral body ratio is determined by the formula a/b. (Reprinted with permission[3])

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Table 1. Entire Group of Athletes (N = 262)

C_4	Mean	Standard Deviation	Range
	0.992	0.096	.66-1.31

Table 2. Athletes with Congenital Cervical Spinal Stenosis

Case	C_4 Spinal Canal (cm)	C_4 Vertebral Body (cm)	Ratio A/B
1. B.S.	2.3	2.9	.793
2. T.S.	2.2	2.9	.724
3. D.O.	2.1	2.6	.808
4. G.P.	2.2	2.9	.759
5. C.J.	2.1	2.6	.808
6. K.J.	1.8	2.5	.720
7. W.B.	2.0	2.5	.800
8. K.D.	1.95	2.85	.680
9. D.S.	2.1	2.6	.808
10. A.S.	1.74	2.16	.810
11. B.S.	2.3	2.85	.810
12. M.S.	1.9	2.35	.810
13. D.A.	2.05	2.50	.820
14. B.S.	1.7	2.5	.680
15. M.I.	2.0	3.0	.666
16. K.B.	1.6	2.0	.800
17. S.B.	1.6	2.0	.800
18. R.B.	1.5	2.0	.750
19. M.K.	1.5	2.0	.750
20. J.S.	1.7	2.1	.809

sagittal diameter of less than 14mm was considered diagnostic of cervical spinal stenosis. The problem encountered with this standard method is that the measurements may be affected by differences in radiographic technique. The ratio method compensates for the variations in radiographic technique because the sagittal diameter of both the canal and vertebral body are affected similarly by magnification factors. A spinal canal: body ratio of 1.00 is normal and less than .82 indicates cervical spinal stenosis according to Torg.[4]

To determine the prevalence of this condition in a large group of athletes, we measured Pavlov's ratio at the fourth cervical vertebra in 122 University of Louisville football players or recruits and 140 Jefferson County high school football players on lateral cervical röentgenograms. The fourth cervical level was chosen, as this typically represents the narrowest level of the cervical spinal canal.[2] At the time of measurement, none of the players had experienced symptoms consistent with a neurapraxia of the spinal cord, ie, transient paresthesias or paralysis of both arms, both legs or all four extremities.

Results

The statistical analysis for the athletes evaluated by the ratio method is shown in Table 1.

Twenty of the 262 players had a canal ratio of .82 or less, a value consistent with cervical spinal stenosis. These values are shown in Table 2.

Subsequent to these determinations, two players experienced episodes of cervical cord neurapraxia. The remainder of the group did not experience such an episode.

Case Histories

Case 1 In October 1988, A.S. suffered a hyperflexion injury of the neck when toppled by several players in a pile-up. This player experienced complete quadriplegia lasting approximately 2 minutes. This motor return was complete. This player's ratio was .81.

Case 2 In June 1989, M.I., an incoming freshman scholarship player, was playing in a high school all-star football game when he suffered a helmet-to-helmet collision with an oncoming opponent. He was also presumed to have hyperflexed his neck. This player experienced numbness in both arms for about 3 minutes, but no motor weakness. This player's ratio was .66. He subsequently underwent evaluation with CT, MRI, and flexion-extension x-rays without findings of associated pathology.

Discussion

Cervical spinal cord neurapraxia is characterized clinically by an acute transient episode of cervical cord origin involving bilateral sensory changes and motor paresis of the arms, legs, or both. This occurs when the athlete sustains a forced hyperflexion, hyperextension, or axial load injury to the spine. Torg reported the incidence of transient paresthesia at 6/10,000 and transient paresthesia with quadriparesis at 1.3/10,000 in a population of football players.[3] One of each of these entities occurred in our population.

In this study, of 262 football players, 20 had radiographic evidence of stenosis of the cervical spine at the fourth cervical level. This prevalence

is higher than we would have suspected, although the mean ratio of .992 is somewhat higher than the mean ratio of 49 controls Torg measured at .973.

This study suggests that the prevalence of congenital or developmental cervical stenosis is reasonably high.

At present, congenital or developmental stenosis has been associated with the occurrence of cervical spinal cord neurapraxia. No association between cervical spinal neurapraxia and permanent neurologic injury has been shown.[3] Torg recommends that those athletes with congenital stenosis should be treated on an individual basis.[3]

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Radioneurosurgery Using the LINAC Scalpel: Technique, Indications, and Literature Review

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Two available commercial units for radiosurgery are the modified linear accelerator (LINAC scalpel) and the gamma knife. Advantages of the LINAC scalpel over the gamma knife are its greater accuracy, the availability of a wide range of collimator sizes that allow for a more homogeneous field of radiation for large lesions, state-of-the-art computer software programs, and lower expense. Radiosurgery does not require an incision, is painless, and can be performed on an outpatient basis. It is ideally suited for the treatment of inaccessible, deep intracranial lesions that are radioresistant to conventional forms of radiotherapy, such as arteriovenous malformations, meningiomas, vestibular schwannomas, selected primary brain tumors, and cerebral metastases. Radiosurgery is an attractive treatment alternative to conventional neurosurgery for several intracranial lesions.

During the final 10 years of the second millennium, the concept of the "Decade of the Brain,"[1] conveys an enthusiasm that permeates the neurological sciences. This perspective stems from advances in imaging technology, molecular biology, genetic engineering, neural grafting, and rapid evolution of non-invasive techniques of treatment. This latter development underscores the current treatment of many types of intracranial vascular disease,[2] such as carotid-cavernous fistulas, and arteriovenous malformations (AVMs) by endovascular techniques. Another rapidly expanding area of neurosurgery is radiosurgery, a technique which requires the combined expertise of the stereotactic neurosurgeon, radiation physicist, and radiation oncologist.

The term radiosurgery was introduced by Lars Leksell,[3] a Swedish neurosurgeon, who focused highly collimated, non-coplanar arcs of X-rays on an intracranial target. In each type of unit currently available for radiosurgery, the isocenter of the source of radiation is known. The intracranial AVM or tumor is placed at that point, using stereotactic techniques. Therefore it is possible to administer large doses of irradiation during a single treatment session, without undue damage to surrounding tissues.

The concept behind radiosurgery is entirely different from that of conventional external beam radiotherapy. Standard fractionated-dose radiotherapy makes use of the differential sensitivity of tumor and normal brain tissue to radiation. Replicating tumor cells are more vulnerable to the damaging effects of radiation than are non-replicating neuronal cells. Radiosurgery, however, is usually administered in a single treatment session using relatively high doses, with the results less dependent on differential radiobiological laws and more on radiogeometric factors.

The obvious advantages of radiosurgery over conventional neurosurgery are: (1) no surgical incision is necessary, (2) the procedure can be performed on an outpatient basis, (3) the patient experiences little discomfort, and (4) there are significant economic savings. It has been estimated that the cost of treating a patient with radiosurgery is 30% to 60% less than it would be with the standard craniotomy procedure.[4]

Three sources of focused radiation are currently available for radiosurgery: the LINAC scalpel, the cyclotron, and the gamma knife. The *LINAC scalpel,* a modification of a standard linear accelerator (LINAC), is created by coupling several precision adapters to it. With the addition of

stereotactic localization techniques, this unit is capable of focusing multiple, non-coplanar convergent X-ray beams directed at an intracranial target.

The cyclotron is a unit which generates radiation from *heavy particles*, such as helium ions and protons. Heavy particles lose their momentum as they pass through living tissue, resulting in the abrupt release of high energy radiation (Bragg peak phenomenon). Cyclotrons cost between $25 to $30 million, which precludes their use in most medical centers. At present only a few centers in the United States have a cyclotron available for medical use.

The *gamma knife* contains 201 radioactive ^{60}Co sources which release gamma radiation, focused by collimators ranging from 4 to 18 mm in diameter. These fixed beams are focused to converge on an intracranial target. This system is presently being used in 10 medical facilities in the United States.

Only the Philips radiosurgery unit (which was designed and developed at the University of Florida), the Fisher LINAC scalpel, and the gamma knife have been approved by the Food and Drug Administration (FDA) for therapeutic use. Other units of lower precision are commercially available but, as yet, have not received FDA approval.

Several comparisons can be made between the LINAC scalpel and the gamma knife (Table 1). The overall cost of the respective units is a major factor, considering the current emphasis on cost containment. Installation of the gamma knife costs $4 to $5 million. The half life of ^{60}Co (5.2 years) requires reloading of the gamma knife with ^{60}Co sources every 5 to 10 years, at an estimated recurrent cost of $250,000 to $500,000. Furthermore, as the strength of the cobalt diminishes over time, the duration of radiation exposure must be increased, requiring constant recalculation of dose-rate ratios. The LINAC scalpel costs approximately $750,000 at installation. Inasmuch as its radiation source is produced electronically, there are no major recurring costs, or need for recalculations or increase in exposure time.

The gamma knife is a dedicated radiosurgical unit, whose use is limited to treating only brain lesions. Assuming that 50 patients are treated annually, its projected use is only 1/2 day per week, leaving this costly unit unused most of the time. On the other hand, the LINAC scalpel uses a modified linear accelerator which may also be used for standard radiotherapy 8 to 10 hours per day.

Table 1: Comparison of Linac Scalpel and Gamma Knife

Factors	Linac Scalpel	Gamma Knife
Energy	4-45 MeV (average = 6MeV)	1.25 MeV
Radiation type	Photons (X-rays)	Photons (Gamma rays)
Collimation/isodose adjustments	Extensive	Limited
Number of beams	Arcs	201
Source	Rotated	Fixed
Cost	$.75 million	$4-$5 million ($1/4-$1/2 million for reloading every 5 to 10 years)
Other use of unit	Yes	No
Availability	General	Limited (by cost)
Accuracy	0.2 ± 0.1 mm	± 0.4 mm

It can be rapidly and easily converted to a stereotactic radiosurgery unit in less than 20 minutes. Thus the LINAC unit provides optimal cost effectiveness, with the potential for maximum utilization throughout the day.

The gamma knife is accurate to ± 0.3mm,[4] with an additional helmet docking inaccuracy of ± 0.1 mm (total accuracy = ± 0.4mm). The Philips LINAC scalpel has an accuracy of 0.2 ± 0.1mm, which has been repeatedly substantiated for those units in use in the United States.

The LINAC scalpel is equipped with 12 collimators that range from 10 to 32 mm in diameter in 2 mm increments, while the gamma knife has only 4 collimators, 4, 8, 14, and 18 mm in diameter. Users of the gamma knife must lower the isodose curve to less than the optimal 80% isodose lines (often to 50%) to treat lesions between 18 and 24 mm in diameter. For lesions greater than 24 mm in diameter, the gamma knife must be equipped with multiple isocenters, which create an additional dose of inhomogeneous radiation distributed to the target. This also creates a shallow dose gradient with higher radiation exposure to the normal brain tissue adjacent to the lesion.[5]

Within the past few years there has been an explosive growth in computer software technology. The LINAC scalpel software program has evolved considerably over the past two years. Although one would expect the rate of development of software programming for the two systems would be similar, the gamma knife unit has had a slower development of upgrades in software and related therapeutic flexibility over the past 10 years.[5]

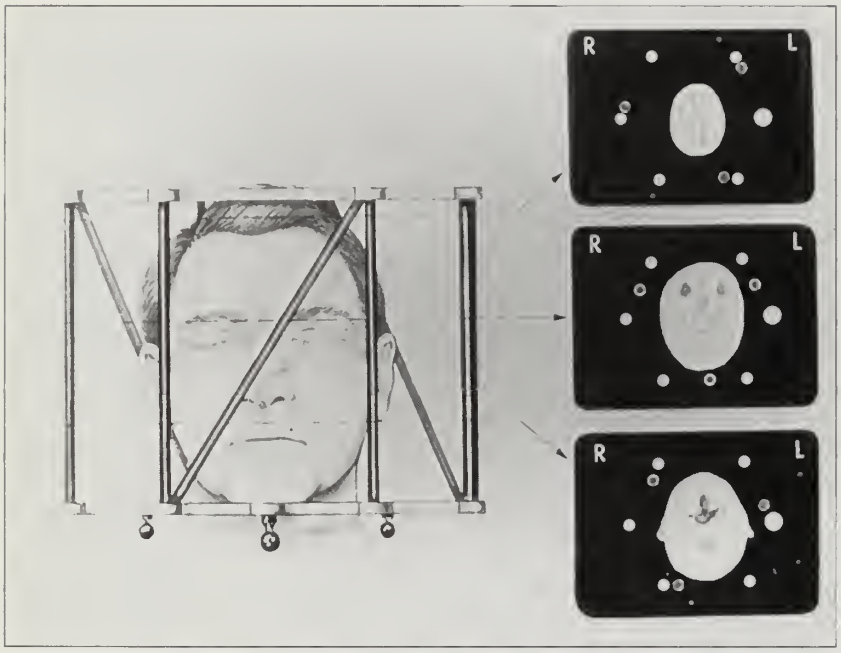


Fig 1 — The CT localizer is attached to the headring. The localizer contains 6 vertical and 3 diagonal rods. An axial CT cut through the localizer yields an image with 9 dots (corresponding to the rods) around the periphery. From the CT scans the intracranial lesion can be converted to stereotactic coordinates, allowing for its precise localization.

LINAC systems range from 4 to 45 million electron-volts (MeV) and are equivalent to the gamma knife with respect to beam energy and dose rate (cGy/min). Dose gradients of the gamma knife and the LINAC scalpel are virtually identical.[6]

Considering several factors: (1) the presence of a linear accelerator at the Brown Cancer Center at the University of Louisville, (2) the greater accuracy of the LINAC scalpel, (3) the therapeutic enhancements offered by regular upgrading of the computer software for the LINAC scalpel, (4) no need for periodic and expensive replacement of the radiation source, (5) and its relatively inexpensive cost, we have chosen the LINAC radiosurgery unit for our use.[5, 7, 8]

Indications for Radioneurosurgery

In general, the standard craniotomy procedure remains the optimal treatment for arteriovenous malformations (AVMs). Immediate and complete obliteration of the lesion is attained with the assurance that it will not rebleed.[9] However, if (1) the AVM nidus is situated in an eloquent or inaccessible region; (2) the patient is >65 years old, medically infirm or poses an excessive risk for anesthesia; or (3) prior surgery or endovascular embolization has failed to cure the AVM, then radiosurgery may be the optimal treatment.

The tumors most frequently treated by radiosurgery are *vestibular schwannomas* (eg, acoustic neuromas or acoustic schwannomas) and *meningiomas*. Ordinarily, these tumors are ideally treated by craniotomy, but for the reasons reviewed above, radiosurgery may be a valuable alternative. Radiosurgery may also be an alternative or supplementary treatment for *gliomas* (astrocytoma or ependymoma). However, such tumors generally have widespread extension, and so radiosurgery is reserved for the unusual glioma that appears to be sharply demarcated on CT and/or MRI scans.[10] *Metastatic tumors* to the brain (particularly melanomas and hypernephromas) can be treated by radiosurgery as a "boost" to conventional whole head external beam irradiation (XRT). Two or three intracranial metastatic tumors may be treated simultaneously, using multiple isocenters during the same treatment period. However, if more than three intracranial metastatic deposits are present following total head XRT, radiosurgery is not considered to be a good treatment option.

Procedure

The patient undergoing radiosurgery is admitted to the hospital outpatient area at 7 AM. A headring is attached to the patient's head using 4 pins placed circumferentially 1″ above the supraorbital line through an area infiltrated with 10 cc of local anesthetic (lidocaine-1%) and epinephrine-0.5%. If an AVM is being treated, biplane angiography of the major vessels supplying the lesion is then performed. A transparent localizing box is attached to the headring during angiography. Following angiography, an enhanced CT scan is performed with a CT localizing frame attached to the headring. This frame consists of 6 perpendicular and 3 oblique radiopaque bars which are projected onto each CT scan (Fig 1). A series of 1.5 mm thick CT slices are performed passing through the lesion. For brain tumors, only an enhanced CT scan is performed. Recently, MRI scans have been utilized for treatment planning, for which a special non-metallic ring is required. After the diagnostic tests are completed, the patient is transferred to his/her room while treatment planning is being carried out.

The treatment planning session requires the

expertise of three specialists: a neurosurgeon, a radiation physicist, and a radiation oncologist. This evaluation and planning stage may last 1/2 to 2 hours. Information derived from the CT scan is transferred to the computer by a magnetic tape. The stereotactic coordinates of the lesion are calculated from the images obtained by the CT scan. The anterior, posterior and lateral angiogram films (if performed) are placed on the digitizer screen and each of the fiducial markers and the AVM nidus are manually outlined. These data are transferred to the computer, from which the treatment plan is developed. The plan usually consists of 4 to 9 non-coplanar radiation arcs, resulting in a total dose of 10 to 20 Gy at the 80% isodose line. To avoid severe complications such as radionecrosis, the amount of radiation emitted by each arc is adjusted so that no more than 800 cGy in toto pass through critical structures such as the optic nerve.

When the treatment plan is finalized and printed, and the patient is transferred to the LINAC unit (Fig 2), using a phantom frame, the correct positioning of the headring is reconfirmed. The LINAC treatment takes 30-40 minutes (Figs 2 & 3). Following treatment, the headring is removed, the patient is kept under observation overnight, and is discharged from the hospital the following morning, after an "18 hour" admission.

Gadolinium-enhanced MRI scans are performed every 6 months following radiosurgery. If there is no evidence of blood flow through the AVM noted on the MRI,[11] angiography is performed to confirm its obliteration.

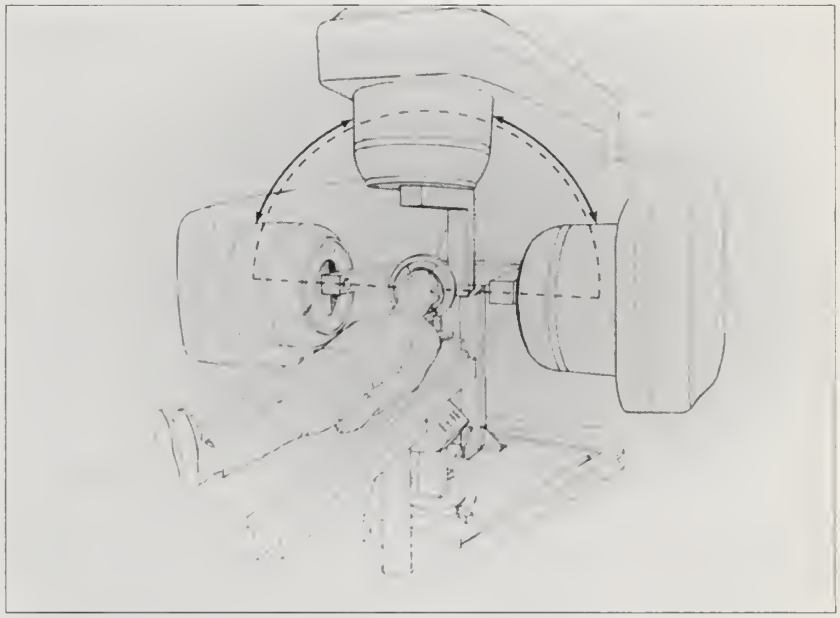


Fig 2 — The LINAC radiosurgery unit utilizes a linear accelerator as the source of radiation. Using stereotactic localization, the intracranial target is placed at the isocenter of the beam generated by the LINAC.



Fig 3 — Diagrammatic representation of several non-coplanar, convergent X-ray arcs focused on a single intracranial isocenter.

Discussion

As the radiosurgical unit at the Alliant Health System and Brown Cancer Center has only been operational since December 1991, no long term results are available. In other series, however, the long term outcome following radiosurgery has been similar regardless of the radiation source used, ie, whether the LINAC scalpel or the gamma knife was used. For patients with AVMs treated by radiosurgery, angiography performed 1 year following treatment showed an occlusion rate of 39% to 52%,[12, 13] and at 2 years the occlusion rate was 67% to 100%.[12, 14, 15] The AVM can rehemorrhage until it has been totally obliterated. Both the natural history, and the postradiosurgery incidence of AVM hemorrhage has been reported to be 2% to 4% per year.[16, 17, 18] The incidence of rehemorrhage and mortality is felt by some to be lower following radiosurgery, even before total occlusion occurs.[16, 17, 19] Radiosurgery acts by inducing a thickening of the vessel walls, creating a gradual vascular occlusion similar to that produced by endarteritis obliterans.[20]

Approximately 15% of *vestibular schwannomas* removed by surgery recur.[21] In these cases, response to radiosurgery is gradual and evolves over a 6-18 month period. A decrease in tumor size occurred in 55% to 58%, with no change in 42% to 43%, of 111 patients in 2 series (26 and 85 patients respectively), followed for 8.3 to 12 months.[22, 23] Contrast enhanced MRI or CT scans showed a decrease in central enhancement in 82% of these lesions, and no change in 18%. The incidence of hearing loss following treatment with radiosurgery is the same as for microsurgery for small vestibular schwannomas. In one series, 7 patients had good or serviceable hearing before treatment with radiosurgery, but only 3 patients had serviceable hearing an average of 7 months posttreatment.[22] If normal hearing was present at pretreatment, Noren et al noted preserved hearing in 56% of patients at 1 year, 54% after 2 years, and 28% after 6 years following radiosurgery.[24] Flickinger et al reported hearing was maintained in 46% of all patients, and in all patients with acoustic neuromas (vestibular schwannomas) of <10 mm diameter.[23]

Early experience suggested that normal facial nerve function might be preserved following treatment of vestibular schwannomas with radiosurgery; however, the incidence of transient facial paresis is 23%.[22] If facial nerve paresis developed postradiosurgery, evidence of recovery was present within 3 months of onset, and full recovery was present between 6-12 months.[22, 25] Flickinger et al reported that 14 out of 46 patients with previously undetected facial weakness developed facial weakness postradiosurgery.[23] Virtually all patients who developed facial nerve weakness following radiosurgery recovered completely if facial nerve function was intact before treatment.[22, 23, 24] Facial numbness (trigeminal nerve damage) occurred in 27% to 28% of patients following radiosurgery of vestibular schwannomas in patients without prior facial numbness. However, all of these patients recovered partial or total trigeminal nerve function within 6 to 17 months.[22, 23]

The indications for surgical treatment of *meningiomas* are identical to those for vestibular schwannomas. This benign tumor is generally situated superficially, and is ideally suited for treatment by conventional neurosurgery. However, a meningioma cannot always be completely resected due to its adherence to critical structures. Overly aggressive attempts to remove a meningioma that is attached to the base of the skull, a venous sinus, a carotid artery, or optic nerve may result in irreversible deficits. Following "gross" total removal of a meningioma, the recurrence rate is 4% to 9%.[26, 27] Engenhart et al reported in 1990 that 20% to 22% of the meningiomas, thought to be totally removed, had recurred by 10 years.[28] Incomplete tumor resection resulted in increased growth in 37% of patients at 5 years, and 91% at 15 years follow-up.[29] Meningiomas have been considered to be "radioresistant" to the standard forms of radiation therapy. Engenhart et al treated 17 patients by radiosurgery who harbored an unresectable meningioma.[28] Utilizing high doses of radiation (up to 50 Gy), 8 out of 10 patients experienced some degree of cerebral radionecrosis, with one of the 8 dying as a result of uncontrolled radionecrosis. In spite of this poor outcome they continue to recommend single high dose radiosurgery for unresectable meningiomas. Kondziolka et al treated 50 patients with meningiomas.[30] They examined 24 of these patients between 12 and 36 months following treatment, who showed a reduction in tumor volume in 13 (54%), no change in 9 (38%), and an increase in 2 (8%), of meningiomas followed for 12 to 36 months after radiosurgery. The two patients who showed an increase in tumor size originally had large tumors, a portion of which were outside the radiosurgery treatment area. Of the 26 patients followed for 6-12 months, 4 showed a decrease in tumor size and 22 showed no change in size.

Metastatic brain tumors usually derive from lung, breast, kidney, or skin cancers. Metastatic cerebral deposits tend to be multiple and are usually associated with much edema. Lesions <0.5 cm in diameter often cannot be identified even when enhanced high resolution CT or MRI scans are used. The diagnosis is confirmed by tumor resection or stereotactic biopsy. Following surgery, the first line of palliative treatment is often total head irradiation, with 30 Gy administered over a 2 week period, in fractionated doses. If one or two metastatic deposits fail to respond to radiotherapy (XRT), or new lesions develop elsewhere in the head, further, conventional XRT is limited to a lower, less effective dose or is contraindicated. Radiosurgery to the residual deposits may be justified, without significantly increasing damage to the unaffected brain. Metastatic tumors are amenable to radiosurgery as a result of their spherical shape, frequent small size, circumscribed margin and limited invasion of adjacent brain tissue. Tumors having radioresistant characteristics, such as malignant melanomas,



Fig 4 — The resultant peak dose of many non-coplanar, convergent arcs of X-rays 100° each focused on an intracranial target.

are often ideal candidates for this type of treatment. Following standard XRT to the entire head, Davey and O'Brien[31] treated 14 patients who had 1 to 3 intracranial deposits of malignant melanoma with radiosurgery, using up to 3 isocenters in each instance. Their results were satisfactory, although they used a total dose of radiation considered to be excessive by most radiosurgeons. Coffey et al[32] reported on 24 patients with brain metastases derived from malignant melanoma (10), non-small cell lung carcinoma (6), renal cell carcinoma (3), colorectal carcinoma (1), oropharyngeal carcinoma (1), and adenocarcinoma of unknown origin (3). The majority of these patients received a combination of 30 to 40 Gy whole brain fractionated radiation followed by a 16 to 20 Gy dose boost to the tumor. In a 23 month period (median of 7 months) no patient so treated died from progression of a brain metastasis. Sturm et al[33] stated that the ideal metastatic tumor for radiosurgery is the deep, radioresistant, and inoperable brain lesion. There was a marked clinical improvement in each of his 12 patients, beginning a few days after the treatment. In seven patients followed for more than 3 months, each showed moderate to marked improvement in symptoms arising from the treated lesion. However, four of these patients died from systemic disease not related to their brain metastases.

For certain primary intracranial tumors, such as germinomas, Casentini et al[34] recommend confirmation of the diagnosis by stereotactic biopsy, followed by radiosurgery to the lesion. Conventional XRT (30 to 36 Gy) is then administered to the entire craniospinal axis. All six of their patients with intracranial germinomas treated by this regimen have responded well for a period of more than 6 years.

In the early radiosurgical experience, heavy charged particle radiation was utilized extensively to treat *pituitary adenomas*, and to effect *endocrine manipulation* for cancer of the breast and prostate. Following advances in transphenoidal hypophysectomy and development of adrenal-suppressing drugs, pituitary ablation by radiosurgery is rarely performed today. If a pituitary tumor extends to the suprasellar area, its proximity to the optic nerve and chiasm precludes its treatment by radiosurgery. Even though there is a high dose-gradient falloff, adherence of the tumor capsule to the optic apparatus is associated with a high incidence of radiation damage to the visual pathways. A gap of 5 mm between the dome of a pituitary adenoma and the optic chiasm is the minimum requirement for safe radiosurgery of the pituitary gland.

Patients harboring *gliomas* are not generally considered to be candidates for treatment by just radiosurgery, because these tumors infiltrate extensively, often to the opposite cerebral hemisphere or to the brain stem. The LINAC scalpel may be considered for the treatment of sharply delineated lesions in carefully selected cases as a boost to conventional external beam therapy. Gutin et al[10] used radiosurgery for the palliation of small, deep recurrent lesions which were inaccessible to conventional treatment.

Complications of Radiosurgery

Unlike conventional neurosurgery, complications of radiosurgery usually occur in a delayed fashion, often between 6-18 months postoperatively. Immediate complications are uncommon. They consist of transient *nausea and vomiting* if the radiosurgery is performed on lesions in the posterior fossa. Radiation scatter may involve the area postrema (vomiting center) of the brain stem. Prophylactic treatment with dexamethasone pre-radiosurgery and dexamethasone and droperidol for several days following treatment usually lessens these symptoms.[35] *Seizures* have occasionally

occurred following radiosurgery, therefore loading with anticonvulsants is indicated for those patients who have cerebral hemispheric lesions. This is particularly important if seizures are known to have occurred previously. *Headaches* lasting for 24 hours developed in 6% of the patients reported on by Flickinger et al.[23]

The serious complications of radiosurgery, edema and radionecrosis routinely have delayed onset. Clinically significant complications rarely occur, even though a moderate number of patients may show minor changes on delayed MRI scans performed 4 to 28 months after therapy.[36] Usually these deficits are promptly relieved by glucocorticoid administration (dexamethasone 4 mg QID). To diminish radionecrosis, radiosurgical doses are chosen from below the 1% dose/volume logarithmic graph[16, 17] or below the 3% risk line.[37] If doses lying above these lines are administered, the risk of radionecrosis is greater.

No deaths have been reported as a direct complication of radiosurgery. Thus, the histopathological examination of brain tumors following radiosurgery is extremely limited. Cell death, necrosis, and replacement of tumor cells with fibroblasts is the most likely explanation for the reduction of tumor mass or cessation of growth of these tumors.[24]

Conclusion

Advanced techniques in computer programming have provided the technology to create a highly precise radiosurgical instrument coupled to standard linear accelerators. Advantages of radiosurgery in the appropriate patient are that (1) no surgical incision is necessary, (2) it may be used in the outpatient setting, (3) there is no pain, and (4) there are economic advantages over open craniotomy. This method provides a reasonable treatment option when standard neurosurgical procedures are contraindicated such as the patient's age, health status, and location of the lesion.

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The Results of 20 Years of Family Practice Residency Training at the University of Louisville

Richard D. Blondell, MD; Judith S. Mason, MPS; Stephen W. Looney, PhD; Tina C. James, BA

In response to shortages of generalist physicians, especially in rural areas, family practice residency programs were established at both of Kentucky's medical schools. In 1972 a family practice residency program became operational at the University of Louisville. A study was conducted to determine the effectiveness of this program. We were especially interested in those factors that were associated with a physician's choice to practice in rural or urban medically underserved areas.

The records of the 100 program graduates were reviewed to determine the physician's gender, ethnic background, hometown, and current practice location. A questionnaire was mailed to program graduates to obtain additional information about factors that influence physician practice location. For the purpose of this study, "rural" was defined as a community of less than 25,000.

Sixty-eight of the program's 100 graduates currently practice in Kentucky. Forty-nine graduates serve patients in rural or medically underserved urban areas, and of those, 31 are located in Kentucky. Whites and those from rural hometowns were more likely to practice in rural communities than minorities or those from urban hometowns. However, minorities were more likely than whites to practice in medically underserved urban areas. No association was found between gender and practice location. Initial interest in rural practice and participation in financial aid programs requiring service in a rural area were associated with rural practice location, but participation in rural rotations at the predoctoral or residency training level were not.

We conclude that the family practice training program at the University of Louisville has been successful in training generalist physicians to serve rural and medically underserved urban populations. This success appears to be largely dependent upon the personal characteristics of the individuals and financial incentives rather than the educational requirements of the residency program. The future success of the residency program depends upon the success of medical schools to produce students who are interested in becoming generalist physicians with an inclination to locate in rural areas.

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The 1910 Flexner Report facilitated a revolution in American medical schools that gradually shifted the aim of medical education away from training generalist physicians and toward the training of more narrowly focused specialized physicians. By the middle of the 20th century, shortages of generalist physicians became apparent, especially in rural areas. The "Millis Report"[1] and the "Willard Report,"[2] both published in 1966, articulated the need to train more generalist physicians and served as a catalyst for the formal recognition of Family Practice as a medical specialty in 1969.

Since specialized physicians were observed to cluster around the white heat of medical technology in centralized urban settings, the 1970 report of the Carnegie Commission on Higher Education recommended that undergraduate and graduate medical education be decentralized so that a portion of medical training would take place in rural underserved areas.[3] The belief was that exposure to rural practice as a student or resident would increase the likelihood that the physician would practice in a rural setting. In 1972, Congress enacted the Comprehensive Health Manpower Training Act [Public Law 92-157] to fund the recommendations of the Carne-

gie Commission; this eventually led to the establishment of the national Area Health Education Centers (AHEC) program which supports the education of health professionals in rural and medically underserved areas.

Since training generalist physicians and addressing the health care needs of rural populations are interrelated objectives, Congress enacted the Health Professionals Educational Assistance Act [Public Law 94-484] in 1976. This legislation linked federal financial support for primary care residencies (Family Practice, Internal Medicine, and Pediatrics) with additional funding for the expansion of the national AHEC program. Extensive cooperation was expected between primary care residency training and the AHEC project, but this has met with only variable success.[4]

During this same period of time, Kentucky also experienced shortages of generalist physicians, particularly in rural areas. Kentucky's responses paralleled the national reaction. In 1970, the Kentucky legislature mandated the establishment of family practice residency programs at both the University of Louisville and the University of Kentucky medical schools. Shortly thereafter, increased funding for primary care residency programs was provided through the so-called "Senate Bill 28" appropriations. These efforts were directed at increasing the supply of generalist physicians for Kentucky.

In the mid-1970s, a statewide Area Health Education System (AHES) was established. This was modeled after the national AHEC project and provided support for decentralized undergraduate and graduate medical education. Every year, residents who were supported by "Senate Bill 28" appropriations were required to complete a 1 month educational rotation in the rural areas of Kentucky. These rotations were often coordinated through the AHES. When federal funding was obtained in 1985, the Kentucky AHES was reorganized as part of the national AHEC program.

The AHES, and later the Kentucky AHEC project, also supported rural rotations for medical, nursing, pharmacy, and allied health students. Federal funding priorities encouraged primary care residency programs and the AHEC program to address the needs of medically underserved populations in urban areas and to increase the numbers of health professionals who are members of ethnic minorities.

The Family Practice residency program at the University of Louisville was established in 1972 with one resident, but rapidly expanded. This growth was fueled with federal, state and local funding which complemented revenues generated from patient care. This funding allowed the residency program to expand to its current size of 24 residents, eight in each year of training. The initial Family Practice training sites were located in one community hospital and two outpatient facilities. In 1981, the Department of Family Practice moved into the new University of Louisville Health Sciences Center Complex and fully integrated the residency program into the activities of the medical school. At the present time, the Department of Family Practice is the most active department in the Kentucky AHEC program at the University of Louisville.

In the 20 years since its establishment, over 100 Family Physicians have graduated from the residency program. In 1991, a study was conducted to determine: (1) the effectiveness of the residency training program on training generalist physicians who would provide care for rural and urban underserved populations, (2) the factors associated with medical practice location and style, and (3) if rural rotations through AHES/AHEC have facilitated graduates in locating their practices in rural areas.

Methods

The study consisted of two parts: a review of the program's records and a survey of its graduates. The residency program records were reviewed to determine the ethnic background, hometown, gender, and practice location of the 100 residents who had completed the program prior to January 1992. For the purposes of this study, "rural" was defined as a community of less than 25,000 people, and the federally designated medically underserved areas were used to define "urban underserved" areas.

A survey of the graduates was conducted to determine: (1) the nature of their practice, (2) how well the residency prepared them for practice, and (3) the factors that were associated with the decision to practice in a rural area. In the summer of 1991, an incoming freshman medical student (TJ) designed a questionnaire that was sent to the 95 physicians who had graduated from the residency program as of July 1, 1991. Questions were devised to obtain the following information: (1) age and gender; (2) practice type and locations; (3) settings in which patients are seen; (4) income, type of reimbursement, and hours

worked; (5) general satisfaction; and (6) an assessment of the effectiveness of the residency curriculum. Other questions were asked to gain insight into the influences that might affect the decision to practice in rural or urban underserved settings: the physician's hometown, initial practice plans, and rural rotations. Analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS-X) and StatXact.[5] Fisher's Exact test was used for significance testing in the cross tabulations. These analyses were used to determine what items of residency training would influence a graduate's decision to practice in a rural area or to practice within the state of Kentucky.

Results

Review of Program Records

The review of the program records demonstrated that of the 100 physicians who completed the program prior to January 1992, 79 are men and 21 women. Seventy-eight graduates are white (non-Hispanic European) and 22 are from an ethnic minority (12 Asians, 6 blacks, and 4 Hispanics). Sixty-eight graduates currently practice in Kentucky, and of these, 20 practice in rural communities in Kentucky. In addition, 6 graduates practice in the southern Indiana region near Louisville. Of all the graduates, 45 practice in communities of less than 50,000 and 35 practice in communities of less than 25,000. Five graduates practice in the underserved urban areas of Louisville and 6 graduates are faculty at the University of Louisville and provide service for the medically underserved as part of their teaching responsibilities. Whites are more likely to practice in rural areas than are minorities (Table 1). However, minorities are more likely to practice in urban underserved areas than are whites ($p = 0.0072$). Of the 14 graduates who currently practice in an urban underserved area, 7 (50%) are minorities. Of the 86 graduates who are not currently located in an urban underserved area, only 15 (17%) are minorities. Individuals from a rural hometown are more likely to practice in a rural area than those from an urban area (Table 2). There was no significant relationship between gender and a rural practice location ($p = 0.70$).

Survey Results

Sixty-four percent of the subjects completed and returned the questionnaire ($n = 61$). Eighty percent of the respondents (49/61) are men and 20% (12/61) are women; this matches the sex distribution found in the review of program records.

Of those survey respondents who initially (upon entering residency) were interested in practicing in a rural area, 81% (21/26) did in fact enter a practice in a rural location (Table 3). Sixty-three percent (15/24) of these currently remain in a rural setting. By contrast, of those who initially preferred a non-rural practice, 90% (9/10) went into an initial practice in a community over 25,000, and 100% (10/10) currently practice in this setting. Fifty-nine physicians responded to the questions relating to participation in a financial

Table 1. Current Practice Location by Ethnicity[a]

Current Location	Ethnicity		Total
	White	Minority[b]	
Rural	34 (44%)	1 (5%)	35 (35%)
Nonrural	44 (56%)	21 (95%)	65 (65%)
Total	78 (100%)	22 (100%)	100 (100%)

[a] $p = 0.0003$
[b] Minority is defined as African, Hispanic or Asian descent.

Table 2. Current Practice Location by Geographic Origin[a]

Current Location	Geographic Origin		Total
	Rural	Non-rural	
Rural	16 (57%)	14 (26%)	30 (37%)
Non-rural	12 (43%)	40 (74%)	52 (63%)
Total	28 (100%)	54 (100%)	82 (100%)

[a] $p = 0.0056$

Table 3. Initial Practice Location by Prior Location Interest[a]

Population of Initial Location	Prior Location Interest			Total
	None	Rural	Non-rural	
<25,000	3 (13%)	21 (81%)	1 (10%)	25 (42%)
>25,000	20 (87%)	5 (19%)	9 (90%)	34 (58%)
Total	23 (100%)	26 (100%)	10 (100%)	59 (100%)

[a] $p < 0.0001$

aid program that requires rural service upon completion of the residency program. While only four out of the 59 respondents participated in such an aid program, these four were still significantly more likely to practice in a rural setting than those who did not participate in such a program ($p = 0.016$). Of the four graduates who received such aid, three currently remain in a rural practice.

For this sample, there was no significant association between participation in a rural clerkship during medical school and entering a rural practice upon completion of residency training. A similar result was obtained when comparing those with some type of rural rotation during residency with those who had no rural rotation. However, when asked if rural rotations influenced their decision to initially select a rural practice, 30% of the respondents indicated that these rotations reinforced their rural interest, and of these, 94% did in fact enter a rural practice initially. Currently, only 57% of these individuals are in a rural practice setting.

Sixty-five percent of the survey respondents reported practicing in a private practice, 10% in emergency medicine, 8% in full-time teaching, 5% in a health maintenance organization (HMO), and 12% reported being in other types of practice arrangements. Sixty-four percent of survey respondents reported caring for patients in intensive care units, 56% in nursing homes, and 41% still made house calls. Fifty-one percent indicated that they provided obstetrical services when they initially entered practice, but only 13% still practice obstetrics. Sixty-seven percent indicated that they felt that the residency training adequately prepared them for practice, whereas 15% felt unprepared. A majority of the survey respondents (69%) felt that the residency program should have provided additional training in health care management related to business and finance. Forty-four percent expressed a need for more clinical training, specifically: colposcopy, sigmoidoscopy, dermatology, emergency and critical care, orthopedics, neurology, pediatrics, and obstetrics. Twenty-six percent reported a need for more surgical training, particularly trauma, plastic surgery, and minor surgery or office procedures. Sixty-five percent of the respondents reported having income in excess of $90,000 a year and 25% reported an income in the $60,000 to $90,000 a year range. Seventy-one percent of the graduates who responded to the survey were satisfied with their current income level and 79% were satisfied with their overall professional life.

Conclusions

The residency program has been successful in training physicians for Kentucky since over two-thirds of the graduates currently practice in the state. Nearly three-quarters of the graduates practice in Kentucky or in nearby southern Indiana. It has been observed for some time that there is an association between the site of graduate training and practice location.[6] However, it is an open question as to whether the location of training influences or is influenced by the physician's preferences for practice location.

Almost half of the program's graduates care for patients in areas that have traditionally been medically underserved. This study provides clues as to which residents, at the time of entry into the residency program, are likely to serve these patients upon completion of the program. Whites, those who are from rural areas, those who have an interest in rural practice, and those who participate in rural scholarship programs are more likely than others to practice in rural communities. Physicians from ethnic minorities are more likely than whites to practice in medically underserved urban areas. On the other hand, gender was not associated with practice location. Other investigators have observed these same associations between background characteristics and practice location.[7] We also found that rural rotations do not seem to influence physicians to practice in rural locations. Thus, it appears that our success in training physicians for underserved areas has rested not so much with graduate education per se, but with who is recruited into the program. This is not to say that rural rotations should be abandoned, since they appear to reinforce the residents' initial desires for a rural practice location and discourage these individuals from changing their plans to practice in rural areas. Moreover, it is difficult to imagine how physicians can be adequately prepared for the realities of a rural practice if they have not spent some time in a rural setting during residency training.

The residency program has generally been successful in preparing graduates for their chosen careers, although not all of the program graduates practice as office based family physicians. Most graduates report being satisfied with their professional lives. Many of the deficiencies of the program identified by the survey respondents have been corrected. Federal residency training grants have been a valuable resource in accomplishing this.

Past success does not guarantee future suc-

cess. Medical student interest in a career in primary care appears to be at an all-time low.[8] Over the past decade the national fill rate for residency positions in family practice has demonstrated a downward trend.[9, 10] University based programs have generally fared worse than community hospital based programs. These same trends have been observed in internal medicine and pediatrics. Without adequate numbers of medical students who are willing to become family physicians, family practice residency programs cannot be successful. Kentucky has mirrored these national trends, although both the University of Louisville and the University of Kentucky send a greater percentage of their graduates to family practice residencies than the national average.[10] Unfortunately some of these graduates have been lured to the vacant family practice positions in other states and do not return to Kentucky to practice. Selective medical school admission policies and changes in medical school curricula have been demonstrated to have the ability to increase the number of students who will choose to enter primary care residencies and eventually practice in medically underserved areas.[11, 12] The University of Louisville is in the process of changing its admission policy and altering its curriculum to increase the number of students who enter primary care residency programs. In addition, both of the state medical schools participate in the Professional Education Preparation Program (PEPP) which seeks to identify high school students from medically underserved areas who have the potential to become generalist physicians and provide them with support to increase the likelihood that they will apply to and be accepted by medical school. It is felt that these individuals are apt to return to practice in the medically underserved areas of Kentucky. The first groups of these students have recently completed college and medical school. Twenty-four out of 27 are currently receiving training in primary care residencies.

Federal support for primary care residency programs has been steadily reduced over the past decade.[13] There have been similar reductions in the state's "Senate Bill 28" appropriations as well. It will be difficult to continue to train residents with fewer funds. Federal policy makers have recommended that additional financial incentives for primary care training be established and that scholarship and loan repayment programs should be directed toward the medically underserved areas of greatest need.[14] Support for physicians who do choose to practice in rural areas is also important.

This study of family practice residency graduates indicates that the national and state efforts described above are an appropriate way to guarantee that the residency program will continue to be successful in training physicians for Kentucky's medically underserved. The greatest challenges that face the residency program are the ability to continue to attract students into the program and the ability to receive adequate funding to support its educational activities.

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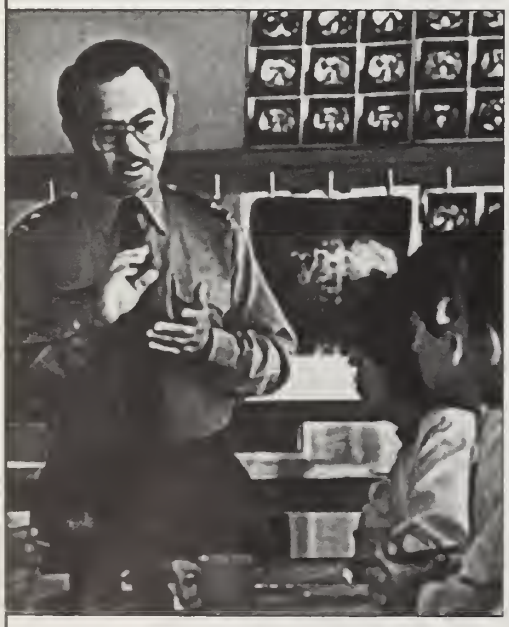
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Sexual Harassment of Female Physicians by Male Patients

TO THE EDITOR: *Sexual harassment (SH) by male patients towards female physicians exists although it has not been as thoroughly and systematically explored as SH by men in general. It is experienced by approximately 25% of women residents. It manifests as staring, hissing, whistling, or a variety of sexual remarks. Unless the patient is confronted and the consequences of such improper behavior are delineated and enforced, the physician may become doubtful about her professional role, self-conscious about her appearance, or even depressed.*

Hospitals need to have specific policies in this regard. Male physicians need to be aware of this phenomenon so as not to minimize or deny it when it happens to a supervisee or colleague and to ensure their relationship with women physicians does not legitimize and/or reinforce patients' actions.

Sexual harassment (SH) is defined as "a specific form of gender discrimination characterized by unwelcomed sexual advances, requests for sexual favors, and other verbal and physical conduct of a sexual nature . . . "[1] Acceptance of that conduct is made a prerequisite for training, job advancements, etc. Although most of the literature has focused on sexual harassment by colleagues and employers, the area of SH by patients has not received that much attention.[2] Since nowadays women constitute 30% to 40% of the first year class in medical school,[2] it is expected that the number of male patients who will receive medical care by female physicians will increase also. Consequently, men treated by females will enter that relationship with preconceived notions, stigmas, and biases towards females in general and professional women in particular that may emerge during treatment as SH. This paper describes the SH that some physicians experience, its characteristics and impact on the physician.

Female physicians relate professionally to men at a minimum of three levels:

- with colleagues at the same professional level
- with other physicians at higher professional levels, ie, attending, department chair, or dean
- with patients

This last relationship is in a category by itself, ie, the healer and the unwell. The interaction between physician and patient is qualitatively different from that between employer-employee and supervisor-supervisee. Therefore, the previously mentioned definition of SH is only partially applicable to this group: these women physicians are in a position of control and the men as their patients are in no capacity to grant favors such as promotions, salary increase, etc. SH by male patients towards female physicians is characterized by sexual remarks, staring, suggestive gestures, deliberate touching, whistling, hissing, turning around and staring.

Epidemiology

SH by patients has been reported by 25% of women residents as gathered in the national survey on stress by Batchelor and Dickstein.[2] A study of female junior house officers by Firth-Cozens showed that the third highest level of stress was caused by prejudice from patients. The first one was conflict between career and personal life, and the second was sexual harassment. Physicians who were victims of prejudice, sexual discrimination by senior physicians, and stress due to conflict between career and home life suffered also from depression.[3]

Age has been described as the most important predictor of SH[2]; SH by patients seems to follow a similar pattern. The sexually harassed physician is usually a young resident, who can be considered attractive by common American standards of beauty. She has less authority and power than a staff member. The harassment occurs under different circumstances, but usually when she walks by and hears a whistle or hissing. Comments are made in regard to her appearance, for example: "nice legs," "I could have a piece of that." Sometimes nothing is said, but the physician has clear awareness of a stare or look of a sexual nature. The harasser may call her by first name, stare into her eyes in a romantic, dreamy way, or touch her in an inappropriately friendly manner.

SH by patients is similar to street harassment: it is brief, the type of comments and behavior are alike, and the man is in no position to grant favors. The harassment can also take place in a group context, where the man is empowered by the presence of "buddies," his accomplices, who silently smile and sneer. A woman may feel as if she were walking inside a bar or past a construction site.

Physician's Response to the Harassment

The physician may feel angry, surprised, used, abused, threatened, afraid, and/or repulsed. SH is a source of stress that can have cumulative effects and damage a woman's self-image, rob her of her privacy, and undermine her confidence in herself as a woman and physician.

Those women who identify and confront the perpetrator feel more in control and better about the way they handle the abuse; the harassment usually stops after this happens. Many women may take "positive" comments as compliments because of

learned beliefs. This will prevent them from taking action against unsolicited remarks, thus the harassment continues.

Those who ignore the harassment, out of fear, inability to identify the patient, a need to be always "nice," or who deny that it is an offensive action, may begin to doubt their role as physician, become self-conscious about clothing, lose interest in coming to work, and may erroneously blame the harassment on themselves.

Profile of the Harasser

The therapeutic relationship is threatened when a patient shows disrespect to a physician because of her sex. The patient's biases and stigmas toward females are projected onto the physician. She may be perceived as powerful and in control, which is threatening to some men. The verbal abuse and/or attempts at physical contact help the man regain a sense of control and masculinity. By making derogatory comments and robbing her of her professional identity, he decreases his outer anxiety, feelings of inadequacy, and of being controlled by someone perceived as inferior but dangerously powerful.

The majority of these men hold traditional views in regard to men's and women's roles in and outside the home. Many behave in a chauvinistic way, where women are objects to possess/discard. In such men a young woman physician elicits insecurity, doubts about masculinity, and threatens their self-esteem.

The attempt to flirt with the physician will give this man a sense of worth, and increase self-esteem temporarily. The indifference, anger, and/or disgust on the part of the physician increases self-doubt and feelings of inadequacy, and he may then gravitate towards his peers to seek support. As a consequence, harassment occurs in a group where the harasser remains anonymous and supported by his peers. The harasser may be obsequious, ingratiating, and inappropriately friendly with his physician while harassing others.

Recommendations

It is imperative that the physician share these incidents with a supervisor. A female role model is of paramount importance, not only to facilitate communication but also for support, guidance, and suggestions. The physician's answers to the harassment will not immediately change old patterns of behavior, but will point out the inappropriateness of it and will help her self-esteem. Harassment needs to be further discussed with the treatment team and the patient must be confronted. If the patient cannot be identified, the issue should be discussed in a community ward meeting.

Hospitals need to develop rules and policies that deal with sexual harassment from patients towards staff. What sexual harassment is, and the consequences of such behavior, should be clearly delineated in the admission information package to which all patients have access.

Finally, male physicians need to be aware of this issue. Their sexual harassment towards their colleagues in front of patients will validate patients' views by having a male role model in a position of authority behaving in an inappropriate and unacceptable manner.

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A Preliminary Evaluation of the Effectiveness of Standard Data Base Software Applied to The Problem of Maintaining Patient Records on a Personal Computer

TO THE EDITOR: *A variety of software[1-13] has failed to provide both a powerful and practical tool for maintaining and analyzing patient records using the personal computer (PC). In order to provide a practical alternative to custom written data bases, an attempt was made to place office records on the standard data base, "Alpha 4." This attempt was not successful, but has led to a better understanding of what such a practical system will entail.*

For at least 30 years physicians and computer workers have been attempting to apply the computer towards the analysis of data generated by the physician-patient encounter. One such system, COSTAR, is an established system with a great deal of flexibility. However, it is an elaborate system and its implementation is not simple.[1] A variety of systems have been and continue to be developed.[2-10] These efforts have attracted the attention of the Joint Commission on the

Accreditation of Health Care Organizations.[11] The COSTAR system originally was developed for medical information to be recorded either on paper forms by the physician or through physician dictation. Data entry would then be done by a clerical staff. This system has been modified over a time to allow many visits to be handled by check off from precoded items on "Encounter Forms."[12]

The corollary of all these systems has been the availability of both administrative and technically expert personnel to custom design powerful systems. This separates the physician who is both the producer and consumer of this knowledge from direct interaction with the computer.

An attempt was made to circumvent the limitations of this approach and to create both a powerful and practical system that could be directly manipulated by a physician with only a moderate degree of knowledge regarding the PC. A standard software data base, "Alpha 4," was chosen because of the possibility that it could be easier to use than other popular standard data base software systems.

Materials and Methods

"Alpha 4" Data Base Software package was installed on a Tandy 1000 TL/2 computer modified with a hard drive. A data base consisting of 21 Alpha numeric fields and 12 logic fields was created (Table 1). One additional "memo" field was created. Over a period of about 7 months, about 2200 entries were made into this system. Data entry was accomplished by handwriting a string of information entries appended to the sheet normally maintained for billing information on the patients. After the billing department had received this sheet, a copy was circulated to the data entry person who was familiar with my style of entries and would enter the information in a very efficient and straightforward way into the data base. With practice, the time to write these entries took no more than 15 seconds. Most patients had between five and ten words or logical entries per visit.

Results

Over a period of about 6 months, about 2200 entries were made into this system. The results of this simple system were encouraging, but were not satisfactory to replace a full written record. After analyzing the problems with this system, they were listed:

1. The development of such systems will be evolutionary rather than revolutionary: it will be best served if large numbers of physicians come to grapple with these problems through individual methods.
2. The patient encounter must to some extent be adapted to the machine. Text based records and text based thinking cannot be simply transferred to machine methodology. Likewise, the paper chart itself has become almost useless: it is more a legal and administrative document than a functional medical document.
3. The entry of data into the system will best be eclectic: some information can be gathered by ancillary personnel or by direct patient computer contact both before and after the physician encounter. Likewise, the use of preprinted forms possibly using barcode scanners or graphic scanners could allow physicians to enter standard information such as ICD-9 numeric diagnosis codes directly into a system within a matter of seconds without an elaborate intermediate clerical staff.
4. Fast and efficient hardware and software, possibly UNIX based, are necessary for this process; for instance, at this hospital about 200,000 patients are on file with probably thousands of data entries in each record. Only through the elimination of the least important information can this data be rendered into both a practical and powerful system for data analysis. The potential benefits include the improvement of patient communication, the promotion of quality improved tracking of patients, improvement in clinical efficiency, improvement in clinical revenues, improved education of residence, research activities reporting, etc.[13]
5. Such a system must allow for comprehensive surveillance of treatment options in patient groups as well as the tracking of family groups. The impact of illness in the individual as it relates to the prognosis of genetic relations as well as to

Table 1

1.	Numbers	
2.	Date	
3.	Last Name	
4.	First Name	
5.	Age	
6.	Diagnosis 1	
7.	Diagnosis 2	
8.	Diagnosis 3	
9.	Finding 1	
10.	Finding 2	
11.	Finding 3	
12.	Maintenance 1	
13.	Maintenance 2	
14.	Maintenance Date 1	
	Work Family Social	Social Operators
	Cigarette Miner Compensation Narcotics	Logical Operators
15.	Med 1	
16.	Med 2	
17.	Med 3	
18.	Numerics 1	
19.	Numerics 2	
20.	Family History 1	
21.	Family History 2	
Memo		
LX5		

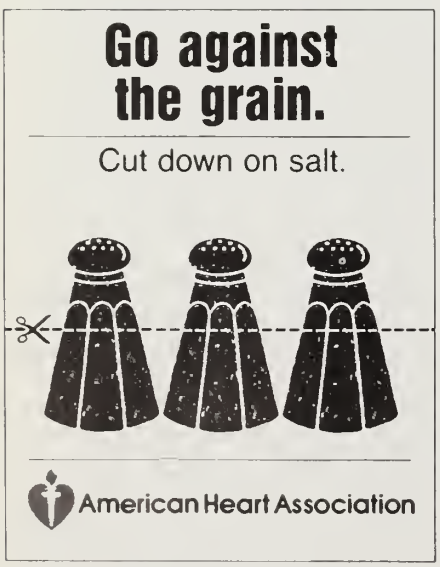
members of the immediate community may have been underestimated because of the lack of such systems.

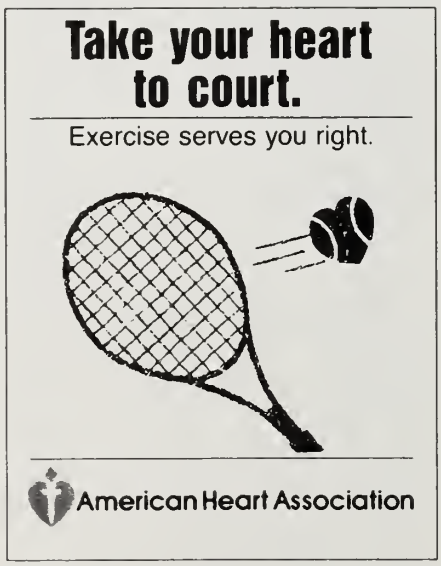
6. Physicians must arrive at a consensus about the nature and use of electronic patient records since legal changes will be necessary to allow maximum utilization of this information. Some but by no means all of this information can remain confidential because of the impact of one individual on the society around him.

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- They want to be kept informed about specific issues;
- They want to fight unfair legislation;
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However, though people join a number of organizations, most become active participants in only a select few. All of us must ensure that both the new and current see our organization not as just another organization competing for their time and energy, but as something really special. We must make all physician spouses see the importance of our efforts and make them want to be an active participant in them. As physician spouses, every day we each serve as a liaison between the medical community and the community at large. It is crucial that each of us is kept abreast of what is happening to medicine through our membership and individual participation.

There was a time when the vast majority of Auxiliary members were "traditional" physician spouses, rearing children and managing the household. But today over 50% of our members work outside the home, either in their own profession, in their spouse's offices, or as full time volunteers. With over 40% of new physicians graduating from the medical schools being female, the male spouses must be an ongoing membership emphasis. We need to provide compelling reasons for every physician spouse to want to become part of this service organization. We need to use the talents of each of you, and I have set this tone of involvement as a major goal for this year.

Our organization needs to reach all physician spouses — the career spouse, the widowed spouse, the male spouse, the medical school spouse, and intern and resident spouse.

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Gloria J. Griffin
AKMA President

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28-31 — 87th Annual Scientific Assembly of the Southern Medical Association; New Orleans, LA. Contact: SMA Registration Dept; 205/945-1840, 800/423-4992 or FAX 205/942-0642.

31-Nov 5 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

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14-18 — 97th Annual Meeting of the American Academy of Ophthalmology; McCormick Place, Chicago. Contact: The American Academy of Ophthalmology, Meetings Department, PO Box 7424, San Francisco, CA 94120-7424; 415/561-8500.

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An 81-year-old man enters the nursing home on moderately ascending doses of long-acting oral morphine for pain from a solitary metastatic pelvic lesion, the primary of which is never found. The escalation of his dosage is tempered by his increased somnolence or his decreased blood pressure until he quietly expires.

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James Stacey, a medical writer and reporter by profession, comes to us as a former member of the American Medical Association staff. He is now Director, Department of Media and Information Services in Washington, DC. His entree to the "inside story" came from his access to organized medicine's representatives and administrators, as well as his ongoing experiences with the current milieu. Some 193 pages, including an index, make this book straightforward and intense. His concept is that medicine is the "new temple" and that our entering it will grant us longevity. Such a construct is financed dearly by all, in the hopes that its roof will protect anyone and all under it. Doctors are priests, carrying the analogy further, and their tending to the people is through their use of the religious model. That is, the tithe collected from many people supports and increases the scope of the care given. No control exists over how much the contribution makes the temple larger, more expansive, and more consuming of our resources.

Stacey sees the demise of this "medieval cathedral" and in its place a new temple built with a narrower mission and with fewer caregivers. He counts the waste going on, the patients without care, the burgeoning technology and the money all this costs, and reckons that there is a more efficient way. Of course, he sits in the middle of the raging national debate, almost like the Indian medicine man, with many simplistic solutions. Stacey does distill the essence of the arguments for and against single payers, managed care, and status quo.

I am not certain that other than a vivid portrait of the current medical world, painted on the canvas of 14th century organized Catholic religion, his book adds any new information or solutions. To the degree that compact argument and sharp rhetoric are effective, this lecture in the form of a book is worth several hours of pondering.

Stephen Z. Smith, MD
Book Review Editor



Precious Life

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KMA returns to the Hyatt Regency Hotel and Commonwealth Convention Center in downtown Louisville for this 143rd Annual Meeting.

Hotel and Convention Center

The Hyatt Regency Louisville, located at 320 West Jefferson, is a luxurious 20-story atrium hotel overlooking the Ohio River in the heart of Louisville's business and entertainment district. The Hyatt features The Trellis, a full-service restaurant located on the first level, and The Spire, an elegant revolving rooftop restaurant that offers a delicious lunch and dinner menu and a breathtaking view of the Louisville skyline. All business meetings and food functions will be held in the Hyatt.

It is important that you make your room reservations as soon as possible for this year's meeting by calling the Hyatt — 502/587-3434. ***Please be sure and indicate that you are attending the KMA meeting*** in order to receive ***the special convention rate*** of Single — $71/Double — $81.

Parking is readily available in downtown Louisville. The Hyatt offers enclosed parking for over 640 cars with additional parking available across the street and connected to the Commonwealth Convention Center by a covered walkway.

The Commonwealth Convention Center, located at 221 Fourth Avenue, will host KMA's General Sessions, specialty group meetings, and exhibit hall. The main registration desk will be located in the Convention Center. The Commonwealth Convention Center is one of the most functionally designed facilities of its kind with versatile lighting, computer climate control, and a sophisticated sound system. Complimentary coffee and danish, an exhibitor's lounge, and a snack bar will again be offered in the Exhibit Hall.

KMA Annual Meeting • Sept 27-30 • Hyatt Regency
Commonwealth Convention Center • Louisville, KY

Shopping and Sightseeing

The Hyatt Regency and Commonwealth Convention Center are both ideally located to take advantage of sightseeing, shopping, and dining, and downtown Louisville offers a wealth of things to see and do.

Within a few blocks is the Museum of History and Science with exhibits of modern technology and ancient history along with the IMAX theatre that combines a huge image on a 4-story tall screen with a 27-speaker surround sound system. The IMAX is the only one of its kind in Kentucky, Indiana, and Tennessee. Close to the museum is the Kentucky Art and Craft Gallery featuring works by Kentucky artists. Other downtown attractions include the Kentucky Center for the Arts, Actors Theatre of Louisville, lunch or dinner cruises on the Ohio River aboard the Star of Louisville, the McCauley Theatre, and Louisville Gardens.

The Hyatt Regency and Commonwealth Convention Center are both ideally located to take advantage of sightseeing, shopping, and dining, and downtown Louisville offers a wealth of things to see and do.

Also within walking distance is downtown Louisville's historic district with classic architecture that brings history to life.

Exceptionally fine shopping can be experienced at the Galleria Mall with its 7-story glass enclosed atrium and over 80 retail shops including major department stores and restaurants. A covered skywalk connects the Galleria to the Hyatt Regency Hotel.

Parking and Transportation

Parking is readily available in downtown Louisville. The Hyatt offers enclosed parking for over 640 cars with additional parking available across the street and connected to the Commonwealth Convention Center by a covered walkway. There are numerous CITYPARK and other public parking garages conveniently located throughout the downtown area.

For a fun and fast way to get around downtown, the Toonerville II Trolley is available **free of charge.** Each of the nine trolleys is a detailed reproduction of streetcars used during the turn of the century that feature mahogany seats and woodwork along with gleaming brass hardware. The historic theme is carried out along the trolley route with authentically styled benches, planters, and street lamps.

Make plans now to attend your 1993 Annual Meeting — September 27-30! KMA



The Hyatt Regency Hotel, site of the 1993 KMA Annual Meeting, is located at 320 West Jefferson Street. There is ample parking within a short distance of the hotel and convention center.



Commonwealth Convention Center, located at 221 Fourth Avenue, will host KMA's General Sessions, specialty group meetings, and exhibit hall. The main registration desk will be located in this Center.

Legislative Seminar on Health Care Reform

A capacity crowd of over 200 attended the KMA Special Legislative Seminar on Health Care Reform held at the Hyatt Regency in Lexington on May 19. Special emphasis was placed on Governor Brereton Jones' proposed reform and in defining the major issues as they affect patient care and the profession. Please refer to the captions for speakers' topics of discussion. KMA













CENTER L to R: State Representative Bob M. DeWeese, MD, "Health Care Reform From A Physician/Legislator Perspective"; KMA President-Elect Ardis D. Hoven, MD, Moderator; KMA Secretary-Treasurer William P. VonderHaar, MD, Moderator, KMA President William B. Monnig, MD, "Health Care Reform & KMA Activities," and KMA Board Chairman Russell L. Travis, MD, "The Governor's Plan." BOTTOM L to R: Kentucky Hospital Association Board Chairman Clarence Traum, "Kentucky Hospitals' Response to the Governor's Plan"; KMA State Legislative Activities Chairman Wally O. Montgomery, MD, "Lobbying Your Legislators."

PEOPLE

William T. Applegate, Deputy Executive Vice President of KMA, recently celebrated his 25th Anniversary with the Association. Mr Applegate joined the Executive Staff of KMA in 1968 and was named Executive Director in 1978. A graduate of the University of Louisville, he is an active member of several professional organizations and recently completed service as President of the Professional Convention Management Association (PCMA).

Gerald M. Larson, MD, surgery professor at the University of Louisville School of Medicine, was a recent recipient of the University's Distinguished Service Award. Honored for what several nominators termed an exemplary service commitment, Dr Larson is involved in contributions ranging from medical missionary work in Kenya to volunteer help with homeless men in Louisville.

As a volunteer with the World Medical Mission, Dr Larson took his family to the Kijabe Medical Center for 6 weeks last summer to relieve staff surgeons.

He has served as a board member since 1986 at Cedar Lake Lodge, a nonprofit residential and service facility for adults with mental retardation.

Dr Larson is a volunteer physician for the Morgan Center for Homeless Men, an outreach program of the Jefferson County Medical Society, and has served on the indigent care and medical-legal committees of JCMS.

Mickey D. Anderson, MD, Bardstown, KY, recently received a 3-year appointment as Cancer Liaison Physician for the Hospital Cancer Program at Flaget Memorial Hospital. The Cancer Liaison Program is an integral part of the Commission on Cancer of the American College of Surgeons.

Dr Anderson is among a national network of over 2100 volunteer Cancer Liaison Physicians who provide leadership and support to the Hospital Cancer Program, and other Commission on Cancer activities.

UPDATES

KMA-RPS Governing Council Elects New Officers

The KMA Resident Physician Section Governing Council elected the following officers for 1993: President — **Baretta Casey, MD,** Trover; President-Elect — **Judy Linger, MD,** UK: Chairperson — **Sheryl Schneider, MD,** UL: AMA-RPS Delegate — **Todd Prewitt, MD,** St. Elizabeth's; KMA Delegate — **Robin Floyd, MD,** Trover; Secretary-Treasurer — **David French, MD,** Trover.

Twelve residents serve on the RPS Governing Council, three from each of Kentucky's Residency Programs. The other Council members are serving in Alternate Delegate positions and as Representatives-at-Large.

The Council is working with student leaders on a joint meeting to be held September 28 in conjunction with KMA's Annual Meeting. The meeting will feature a panel discussion on "Changing Dimensions of Medicine" and will focus on the legislative arena, choosing primary care vs a specialty, financing a medical career, and managed competition.

First Meniscus Transplant in Kentucky Performed at UK

UK reports that Kentucky's first meniscus transplant was recently performed on a 39-year-old man at the University of Kentucky Hospital by **David N. Caborn, MD,** assistant professor of orthopaedic surgery and director of UK's sports medicine program. A reconstruction of the anterior cruciate ligament was also performed. Meniscus transplantation is a new and technically difficult procedure which has only been performed at six other sites in the United States — Pittsburgh; San Francisco; Ogden, Utah; Atlanta; New York; and Miami.

The meniscus is a crescent-shaped pad of cartilage which helps to cushion and stabilize the bones of the knee joint, acting as a shock absorber. When the cartilage is damaged, orthopedic surgeons often must resort to cartilage removal which often makes the knee more vulnerable to further tears. In some cases, patients who have lost protective knee cartilage develop crippling arthritis. In severe cases, total knee replacement is recommended.

"Even with the most advanced techniques, only 30 percent of all cartilage tears respond to surgical repair," said Dr Caborn. "This is why we are excited about the potential for this new type of treatment option. We believe it will eliminate or delay a total knee replacement for many patients if performed early."

The recovery period for a meniscus transplant requires that the patient wear a brace with controlled motion and use crutches to walk for six weeks. Although the transplant involves the insertion of donor tissue, research has not indicated that rejection is a major problem.

A scan of the knee before surgery determines the size of the cartilage that is needed and helps in the selection of the donor meniscus. The surgery is performed using live cells from frozen cadaver tissue.

The UK patient is expected to be

totally recovered in 6 to 12 months. Dr Caborn has recommended a period of rehabilitation therapy that involves progressive range of motion, weight bearing, and strengthening to facilitate normal healing.

New Machine Aids in Quick Disease Diagnosis

U of L reports that a new machine in the Department of Medicine is helping assistant professor **Julio Ramirez, MD,** diagnose more quickly diseases such as tuberculosis and atypical pneumonias.

The DNA thermal cycler machine is a new technology that causes a polymerase chain reaction, or (PCR). The process reduces to 2 to 3 hours the time needed for diagnosis of infectious diseases.

"In the case of tuberculosis, a culture of the bacteria usually takes 3 to 4 weeks to grow. Theoretically, using PCR, you could make the diagnosis, isolate the patient, and begin treatment within 4 hours," Dr Ramirez said.

The machine works by amplifying specific pieces of DNA. It speeds up the natural process of DNA replication and uses manmade reagents to ensure accuracy, according to Dr Ramirez, acting chair of U of L's division of infectious disease.

U of L Professor Introduces Rural Medicine

U of L reports that **Ellen M. Joyce, MD,** assistant professor of clinical services for the Department of Family and Community Medicine, recently offered students a rare opportunity. Her Mud Creek Education Project gave individuals interested in health care a taste of practice in a rural community.

On her fourth trip to Mud Creek Clinic in Floyd County, KY, Dr Joyce and the students she took spent a Saturday socializing with the clinic's staff, treating patients from the community, and familiarizing themselves with local people.

"Mud Creek is just one of many rural clinics that could be used as training sites. However, most training still takes place in the city. Innovations in medicine and medical training have made it possible for quality training to take place away from the tertiary care hospital," Dr Joyce explained.

"My goal is to provide a teaching site in a rural area of Kentucky so incoming students, medical students especially, will be able to imagine themselves doing their work in such a community," she continued.

Essential to the program is support from Mud Creek.

Clinic nurse Beverly May lines up patients to be seen by visiting students, and Eula Hall, the clinic's founder, takes students on home visits, tells them stories and fills them in on health care in Appalachia.

"The program has been a tremendous success," Ms May said. "We are so grateful to Dr Joyce for getting the university involved with our community.

"One reason it is so helpful is that we have no female medical providers here. Women patients are hesitant to have a male provider perform an exam. When Ellen and her female students come, the patient sign-up sheet out front always has twice as many names on it."

Ms May hopes U of L students realize the service they are providing the community and clinic staff.

"Even though Ellen and the students come on a Saturday, I never have any trouble getting the staff to come in and work," Ms May said. "Also, the students see a true, community-based clinic.

"We serve everyone, not just the poor. Some think rural medicine is depressing and backward. We want students to see that in a community like this, you can see and feel the difference you've made."

"I want to take medical students who are interested in generalist careers and the people with whom they would work, not necessarily physicians," Dr Joyce said. "These clinics need nutritionists, physical therapists, psychotherapists and people with skills complementary to the generalists."

Dr Joyce practiced medicine at Mud Creek Clinic for 10 years before she came to U of L in 1988. She believes that her relationship with the rural community gave her self-confidence she might not have found elsewhere.

"Working in a rural community can be very appealing. It offers unique challenges and responsibilities. It is possible to find satisfaction and to exercise more of your training in such a setting," Dr Joyce said.

The students who have experienced Mud Creek loved it and want to go back, Dr Joyce said. The professor hopes to take a larger, more diverse group each time she goes. Volunteers will now receive class credit for their participation.

"My goal is to make four trips each year. I hope that this project will be flexible enough that it will expand according to the interests of those wanting to participate," Dr Joyce said. "I also hope to keep Mud Creek involved with the University."

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Fayette

Jonathan E. Hodes, MD — NS
1193 Sheffield Pl, Lexington 40509
1980, Indiana U

Franklin

John K. Shekleton, MD — GE
102 Thistle Rd, Frankfort 40601
1985, Southern Illinois U

Henderson

Edward N. Moore, MD — C
1015 N Elm, Henderson 42420
1984, U of Kentucky

Harlan

Rogelio L. Uy, MD — IM
120 Ivy Hill, Harlan 40831
1978, U of Santos Tomas

Jefferson

Steve M. Audenaert, MD — AN
P O Box 35070, Louisville 40232
1982, U of Mississippi

Michael S. Davis, MD — IM
350 W Broadway #505, Louisville 40202
1988, U of Louisville

Wayne S. Gibson, MD — C
7003 Harrods Landing, Prospect 40059
1983, U of West Indies

Thomas J. Haas, MD — S
4211 Winchester Rd, Louisville 40207
1984, Medical U of South Carolina

Sri P. L. Mokshagundam, MD — IM
7620 Greenlawn, Louisville 40241
1978, Government Medical Col, India

Marcello Pietrantoni, MD — OBG
14805 Forest Oaks Dr, Louisville 40245
1982, Bangalore Medical Col

Jeffrey M. Robbins, MD — EM
614 Executive Pk, Louisville 40207
1981, Nordestana U

Luis M. Velasco-Cervilla, MD — OBG
210 E Gray #706, Louisville 40202
1981, Universidad Central del Caribe

Jonathan W. Wilding, MD — IM
P O Box 6181, Louisville 40206
1989, U of Louisville

Livingston

R. Todd Michael, DO — GP
1972 US Hwy 60 E, Salem 42078
1987, Col of Osteo Medicine, Des Moines

McCracken

John M. Pierce, MD — EM
165 Deerpath Ln, Paducah 42001
1984, U of Mississippi

Northern Kentucky

Stephen G. Moeller, MD — R
170 Barnwood Dr, Edgewood 41017
1984, U of Cincinnati

Melissa C. Smith, MD — OBG
1 Medical Village Dr, Edgewood 41017
1980, U of Massachusetts

In-Training

Jefferson

Lori B. Ensor, MD — AN
Tami G. Hill, MD — PD
Natalie E. Lane, MD — PD
Peter S. Lansing, MD — IM
Bryan A. Loy, MD — PTH
Sudhir M. Narain, MD — IM
Vijaykumar G. Patel, MD — S
Juan S. Sandoval, MD — FP
Monica A. Shaw, MD — IM
Manvinder Singh, MD — REN
Christopher E. W. Smith — S
David A. Spain, MD — S
Mary F. Stephenson, MD — P
Bernard A. Tisdale, MD — ONC

DEATHS

Alfred O. Miller, MD
Louisville
1913-1993

Alfred O. Miller, MD, a retired radiologist, died May 4, 1993. Dr Miller graduated from the University of Louisville School of Medicine in 1939 and was a life member of KMA.

Edward O. Guerrant, MD
Winchester
1908-1993

Edward O. Guerrant, MD, a retired surgeon, died May 9, 1993. A 1932 graduate of the University of Cincinnati College of Medicine, Dr Guerrant was a life member of KMA.

Allen L. Cornish, MD
Lexington
1915-1993

Allen L. Cornish, MD, a retired internist, died May 25, 1993. Dr Cornish was a 1940 graduate of Columbia University College of Physicians and Surgeons and was a life member of KMA.

Carl E. Shroat, MD
Frankfort
1931-1993

Carl E. Shroat, MD, a family practitioner, died May 28, 1993. A 1956 graduate of the University of Louisville School of Medicine, Dr Shroat was an inactive member of KMA.

MARK YOUR CALENDAR

143RD ANNUAL MEETING
KENTUCKY MEDICAL ASSOCIATION
SEPTEMBER 27, 28, 29, 30

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COMMONWEALTH CONVENTION CENTER
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AMA poised to respond to reform plan

The AMA is prepared to respond and communicate to the public, Congress and physicians once Clinton unveils his health system reform package.

AMA leaders will give Association members and patients immediate feedback and analysis of the proposal. The feedback will help them determine if the plan meets medicine's needs.

AMA strategy includes nationwide communications to physicians through an all-physician mailing that will reach the 718,000 physicians and medical students soon after the unveiling.

Also, a broad-based communications program will be executed to give the media and public AMA reaction and views on elements of the proposal. A grassroots strategy is planned for physicians and physician leaders to communicate with Congress.

American Medical Television (on CNBC) will outline the plan's impact on physicians and give physician response.

AMA publications will also compare its elements to those in the Association's own plan, Health Access America.

AMA triumphs, HCFA consultation policy reversed

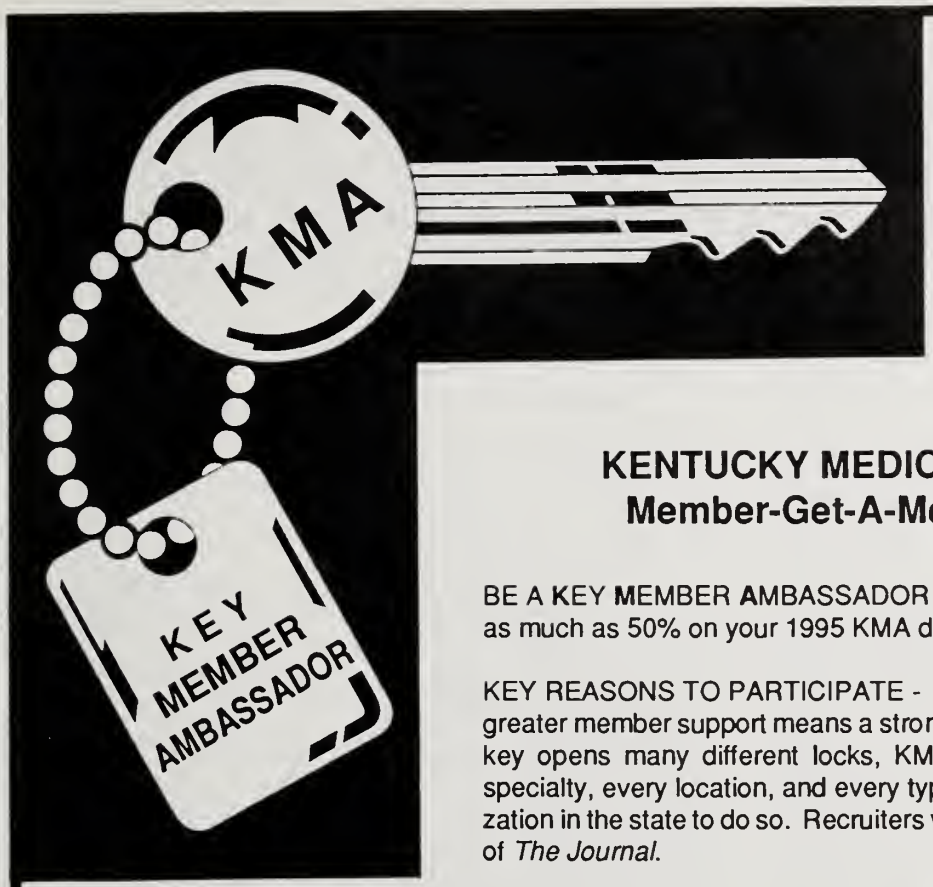
Substantial AMA efforts helped reverse HCFA policies prohibiting primary care physicians from billing for pre- and postoperative consultations.

Effective June 28, the new policy eliminates distinctions between primary care physicians and specialists. It instructs carriers to use the current CPT definition of consultation in determining payments.

A letter from AMA EVP James S. Todd, MD, to HCFA said, "This policy is wrong and must be corrected."

"Current clinical practice includes numerous circumstances in which the surgeon's request to the patient's primary care physician for a pre-operative medical clearance or history and physical constitutes a request for a consultation," Dr. Todd wrote.

Prepared by the Department of Communications Services. For information, call 800 AMA-3211, ext. 4416.



YOU are the KEY to the

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Member-Get-A-Member Campaign

BE A KEY MEMBER AMBASSADOR - and unlock the opportunity to save as much as 50% on your 1995 KMA dues!

KEY REASONS TO PARTICIPATE - Besides the dues incentive to you. . . greater member support means a stronger, more unified, voice. As a master key opens many different locks, KMA represents physicians from every specialty, every location, and every type of practice - and is the only organization in the state to do so. Recruiters will also be recognized in future issues of *The Journal.*

KEY PROSPECTS - New physicians in your area, hospital staff colleagues, alumni from your medical school, physicians in your specialty, or nonmembers in a particular target group, eg, women physicians, faculty, international medical graduates - take your pick.

KEY TO RECRUITMENT - The most effective way to recruit new members is through a **personal** conversation or note conveying your own thoughts about why you are a member. Special recruiter kits containing brochures and information on benefits are available for your use.

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6-9	new members	-	earn a	30%
10+	new members	-	earn a	50%

YES, I'm interested in the Member-Get-A-Member campaign. Send me a recruiter kit.

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Phone _____

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- ❒ In my specialty
- ❒ From my medical school class
- ❒ Faculty at my school
- ❒ Women
- ❒ International medical graduates

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in eny patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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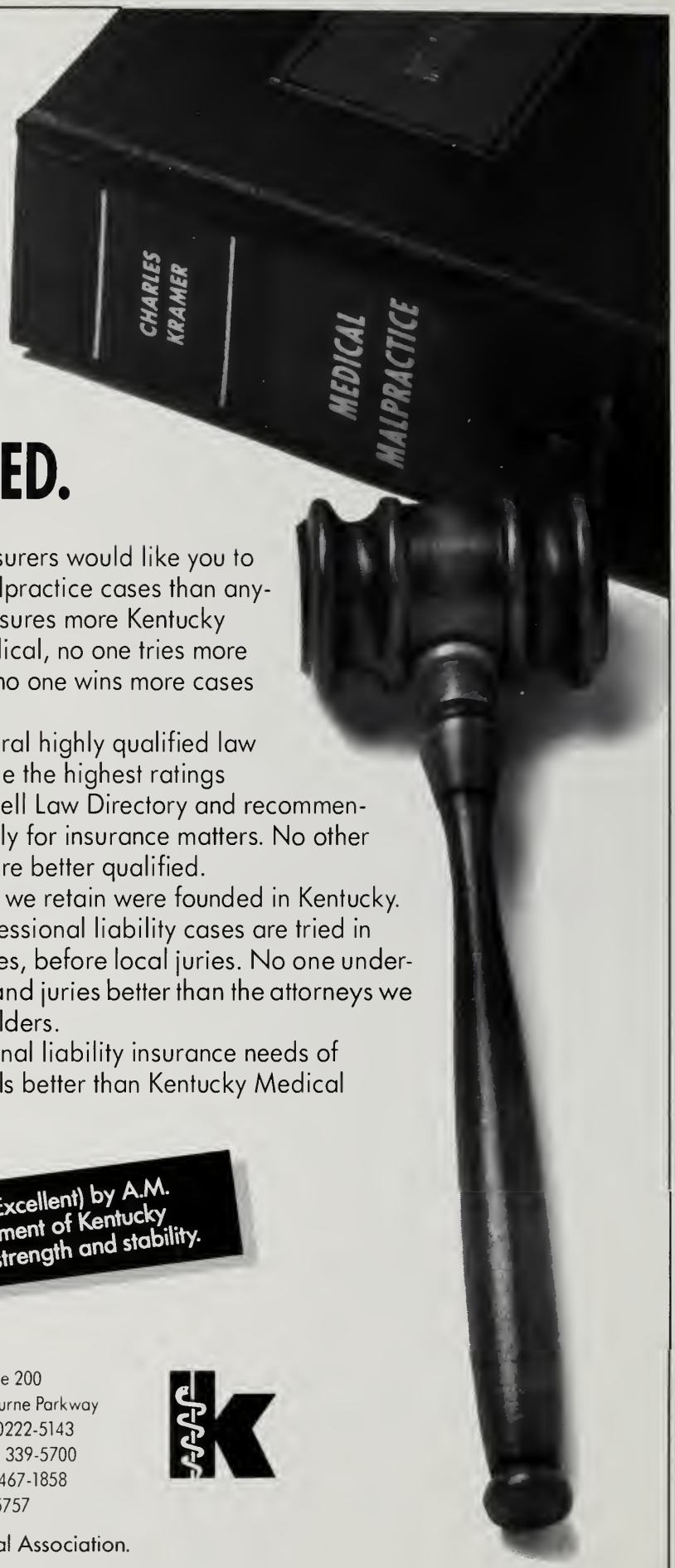


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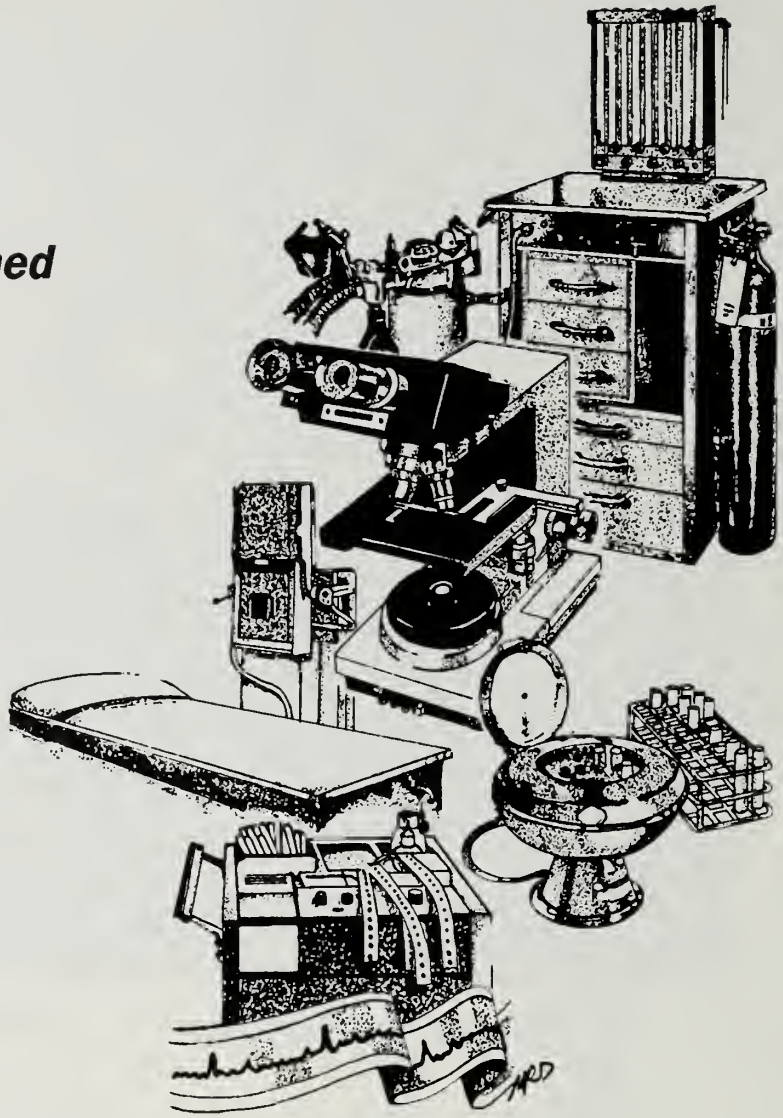
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EDITORIAL

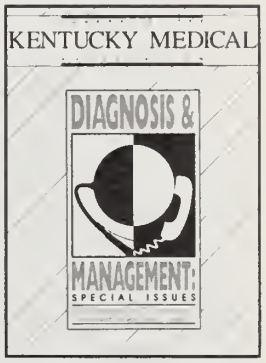
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***COVER:** "DIAGNOSIS & MANAGEMENT: Special Issues" is the theme of this yeor's Kentucky Medicol Associotion Annual Meeting, scheduled for September 27-30 ot the Hyatt Regency Louisville. This month's cover introduces o complete preliminory progrom for this nat-to-be-missed event. Diversity has olwoys morked the scientific sessions of the Annuol Meeting. With the mony speciolties thot sponsor programs during the meeting, attendees can chaose from a wide variety af tapics, speakers, and lecture farmats.*

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We Will Survive



David C. Liebschutz, MD

Medicine, as you and I know it, is under attack. A dark plumb hangs over our head and it appears we are being attacked from the right, the left, occasionally the front, and mostly from behind. Government wants us to "work," help the sick, comfort the oppressed, and make the "lame run." Attorneys would like us to stumble so they can "extract their bitter toll." Patients just want to be cared for without breaking their backs.

Social changes, social reform, medical changes, medical reform — all of this is whirling around our heads. Physicians stand in the center of a whirlpool of social and economic chaos. When the dust clears and we look around, our practices and our outlooks will certainly be different. How we practice medicine, how our outcomes are reviewed, and who is looking over our shoulders will probably be changed. The only thing that will not be different is that "the doctors will still care for patients." The medical profession will care for and do what is necessary to see that those served are served honorably, justly, and reasonably.

A recent article in the *Bulletin of the American College of Surgeons* illustrates that medicine will survive. When Hitler invaded Poland in 1939, his high command decreed that all levels of higher education, including medical schools, would be eliminated. His repressive regime felt that the masses of Poland did not deserve educational enlightenment, nor progressive medical care. The Polish natural identity was to be eliminated. The penalty for continuation of medical education was severe — death.

Yet, from this oppressive environment, medical educators of Poland were able to secretly arrange to teach and educate students so that a supply of medically educated physicians were available to care for the people of Poland during and after this catastrophic war. Dr Rudowski in his *Clandestine Medical Education — Poland 1939-1945* listed many lessons. Those lessons included (1) "Motivation for Medical Training is an inherent sense of values, an historical ethical code, which cannot be suppressed by any military and political power," and (2) "Medicine is deeply rooted in natural sciences, and its progress continually turns to the scientific methods."[1]

Nelson B. Rue, Jr, MD, Kentucky Medical Association President from 1989 to 1990, noted in his President's Page of October 1989 entitled *Decade of Decision* that as the 1980s ended, the 1990s would be a decade of "new beginnings and assessments." He also noted that, unfortunately, many of these decisions would not be ours to make. As we've journeyed 3 years into the "Decade of the 90s," these words ring more true. "We must pursue our practice of medicine, our teaching, research, and development of technology even in the face of our problems, and *to value* this profession as never before."[2]

We, as physicians, carry a great social and ethical burden to care for our patients, and with appropriate medical care for our society. As the politicians nibble at our rears and limit our steps forward, I know that we will tighten our circles.

As the season of the Summer leads into the Fall of the year, the Kentucky Medical Association leadership and the Board of Trustees are working towards the Annual Meeting in September. This last year, the amount of action and involvement of the KMA Leadership and the ongoing saga of Health Care Reform has been extensive. Throughout the year, you've received numerous publications, letters, and Legislative Updates about the happenings and the involvement; thus, I will not reiterate these at this time. The Kentucky Medical Association Annual Meeting this year will be a time of reflection over what has happened in the last year and a time for rededication to the future. We look forward to seeing you at the meeting and being available to answer your questions.

TOGETHER, WE WILL SURVIVE

David C. Liebschutz, MD
KMA Vice President

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Bronchopulmonary Disease: An Association With Ulcerative Colitis and Pyoderma Gangrenosum

Pran M. Kar, MD; George Aronoff, MD; Patrick Schuette, MD

From the Department of Medicine, University of Louisville, Louisville, KY (Drs Kor ond Aronoff), ond the Department of Medicine, Grant Hospital of Chicogo, Chicogo, IL (Dr Schuette).

Bronchopulmonary disease is an unusual association of ulcerative colitis and pyoderma gangrenosum. We would like to report a young patient with a history of ulcerative colitis who developed pyoderma gangrenosum and concomitant bronchopulmonary disease which responded to combined steroid and dapsone therapy.

Case Report

The patient is a 34-year-old black female with a history of sarcoidosis and ulcerative colitis admitted with chief complaints of fever, non-productive cough, and swelling of the left arm for a 1 week duration. The patient was seen by her private physician and a chest x-ray revealed a patchy infiltrate on the left side (Fig 1). She was put on cefaclor, but after taking two doses, she developed vomiting, and could no longer take the antibiotics by mouth. She was therefore admitted to the hospital for intravenous antibiotics administration.

The patient gave a history of diarrhea with rectal pain about 2 weeks prior to admission, for which she had taken two hydrocortisone enemas. The last enema was taken 4 days prior to admission, with resolution of both the diarrhea and the rectal pain. The patient denied any loss of weight or night sweats. She was allergic to piroxicam and doxycycline. Her mother had ulcerative colitis. Her last menstrual period was 6 days prior to admission and the rest of the history was unremarkable. On admission patient was tachypneic, breathing at the rate of 28 per minute, and her oral temperature was 38.7°C. Physical examination showed decreased air entry on the left side of her chest with basal rales and a 3 mm pustular swelling on her left arm (Fig 2) containing clear fluid. Her chest x-ray revealed a left lower and mid-lung infiltrate (Fig 3). Her laboratory data showed a WBC of 15.8 thousand/mm^3 with a left



Fig 1 — Chest x-ray showing an area of infiltration overlying the mid-lung field.



Fig 2 — Vesicular lesion on left upper extremity.

shift. The rest of her laboratory data were unremarkable. Blood, sputum, and urine cultures were obtained, and the patient was started on broad spectrum antibiotics for 10 days. During this time the patient's skin lesion worsened, with an appearance of more lesions at sites of blood draws. Bronchoscopy revealed hyperemic airways. Transbronchial biopsies were taken which showed no granulomas, and bronchoalveolar lavage showed no predominant cell type. The blood, sputum, and urine cultures remained negative. A dermatology consult was obtained. A skin biopsy (Figs 4-7) was consistent with the diagnosis of pyoderma grangrenosum. The patient was started on prednisone 60 mg and dapsone 25 mg on the 10th day after admission. There was a remarkable improvement (Fig 8) in the skin and pulmonary lesions, and a repeat chest x-ray confirmed the findings. Patient was discharged on the 16th day of her admission to be followed up by her own physician. A chest x-ray taken at the completion of 6 weeks of therapy showed complete resolution of the infiltrate (Fig 9) and skin lesions.

The patient has had three recurrences of the lesions, twice with similar chest x-ray changes, and each time has responded to a repeat course of prednisone and dapsone.



Fig 3 — Chest x-ray shows progression of disease with enlargement of right upper lobe infiltrate and progression of left lower lobe infiltrate.

Discussion

The extraintestinal manifestations of ulcerative colitis are cutaneous, musculoskeletal, hepatobiliary, renal, ocular, pulmonary, and hematologic.[2] We would like to focus on the pulmonary and skin complication seen in ulcerative colitis.[1,3] Pulmonary lesions include fibrosis, vasculitis, alveolitis, bronchiectasis, bronchitis, and obstructive disease.[1,2] The patients who have ulcerative colitis and pulmonary lesions have no history of smoking and have had normal chest x-rays in the past. They also have no prior history of bronchiectasis, or any precipitating cause like pneumonia or foreign body aspiration. Alpha-antitrypsin values done earlier on these patients have also been normal.[6] The typical patient of ulcerative colitis with pulmonary involvement presents with cough, hemoptysis, and bilateral pleural thickening with chest x-ray infiltrates, as seen in our patient.[1] A similar presentation has also been seen in sulfasalzine induced lung, but on discontinuation of the drug, improvement is seen, suggesting a possible hypersensitivity lesion.[11]

The skin lesions seen in ulcerative colitis include pyoderma gangrenosum, erythema nodosum, and aphthous ulcers.[2] Pyoderma gangrenosum is a large, suppurative necrotic ulcer with ragged, heaped up, and undermined edges with lymphatic infiltrates and fibrinoid necrosis of the vessel wall and can precede or occur at any stage.[3,4] Virus like particles have been seen in the biopsy material but this has not been confirmed.[12]

Circulating immune complexes and antibodies to the colon cells have been suggested as the possible etiology in the pathogenesis of the skin and pulmonary complications. The titer of the immune complexes have not been seen to correlate with the disease activity.[5] Although, there does appear to be a relationship between the severity of the skin and the pulmonary lesion. Both the skin and the pulmonary lesions can appear even after colectomy, supporting the immune complex hypothesis.[13] A streaking leukocyte factor which increases the migration of leukocytes without an increase in the chemotactic activity has been seen in pyoderma gangrenosum, and may be responsible for the pulmonary lesion as well.[12] The ulcerative colitis precedes the skin involvement and the skin involvement usually precedes the pulmonary lesions. The skin and the pulmonary lesions respond to steroids, because the steroids exert their effect on cell mediated and humoral immunity, and by reducing capillary wall permeability and edema formation.[7,8,10] Dapsone may be acting by stabilizing lysosome and myeloperoxidase-halide system, inhibiting the alternate pathway of complement ac-

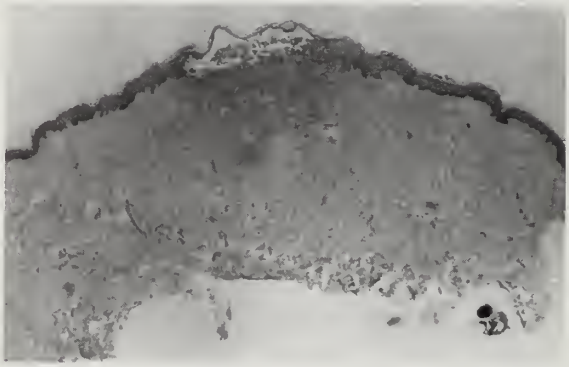


Fig 4 — Photo micrograph showing a vesicular necrotizing skin lesion.



Fig 5 — Vesicular lesion with epidermal surface break.

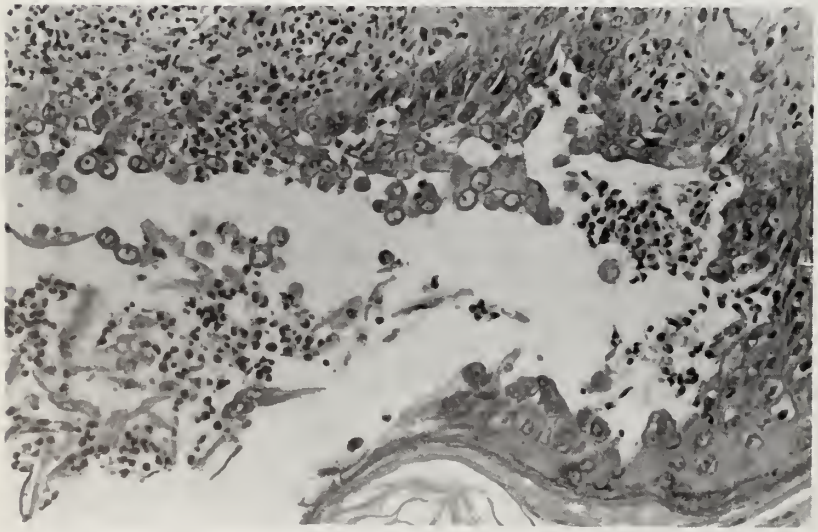


Fig 7 — High power of vesicle with an acute exudate mixed with epidermal and polymorphonuclear cells.



Fig 6 — Intermediate magnification reveals an acute inflammatory cellular exudate and destroyed keratin.

tivation, and acting as an immunomodular.[9]

In our patient, the response of pyoderma gangrenosum and the pulmonary lesions to prednisone and dapsone suggests that the two might have been related. The pulmonary lesions could have been sarcoidosis, but the transbronchial biopsy and the lavage conflict with this possibility. The skin lesion of our patient could have been confused with Lupus Pernio, the sarcoid skin lesion, which is usually a symmetrical, insidious lesion seen on the face, and which rarely resolves.[14] Our patient, on the other hand, had rapid resolution of both the skin and the pulmonary lesion as soon as therapy was commenced.

We therefore suggest that pyoderma gangrenosum, although an uncommon extraintestinal manifestation of ulcerative colitis, can occur, and may involve the lungs. This should be confirmed by appropriate biopsy, and once an infectious cause has been ruled out, the condition should be treated with steroids and dapsone.



Fig 8 — Chest x-ray shows some improvement in the infiltrates when compared to previous films.



Fig 9 — Chest x-ray on completion of therapy.

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A Mnemonic Approach to Health Reform

Many physicians have become disenchanted, disillusioned, and disgusted as they have watched from the sidelines as politicians have been dealing, chanting, and goading the public in the area of health reform. This has caused some physicians to say that the future is dim. They are very concerned about the prospects of what lies ahead for health care professionals.

Borrowing from medical school learning techniques, when we learned the cranial nerves by using mnemonic devices such as . . . "On old Olympus" . . . and "Never lower Tilly's pants" . . . , we'll borrow a mnemonic device to analyze the three S's of health care reform:

First, ***symbolism*** — Both on the national and the state scene, we find President Clinton and Governor Jones appealing to the masses. Health reform is an issue of importance because polls show that people rank it high amongst concerns, fearing a serious illness which would wipe out family resources. If you sit back and watch, we are in a period where the catch phrases "universal coverage," "managed care," "access," "availability," "decreasing costs of care," "too many specialists, not enough primary care physicians" are all symbolic political hot air balloons as our politicians attempt to effect change. However, if one views health reform historically, health reform will come from an evolutionary approach, not the revolutionary approach we see the politicians advocating.

"The States rank first in health care, not because of our wonderful generalists and primary care physicians, although they are essential components of the system, but we rank as tops in the world because of our specialists and high intensity of medical care."

Second, ***substance*** — Even though symbolism is the way the politicians posture for issues that catch the public's eye, the real change will come in a substantive way and that change will occur through constructive suggestions by informed sources, and vested interests such as organized medicine will have an opportunity to make their suggestions. The legislative process by design moves cautiously and slowly. Change will come by amendment and re-amendment, negotiations and compromises. For example, prior to the recent session of the legislature, Governor Jones was adamant that he would not accept anything less than universal coverage. However, he changed his tune very quickly as he started meeting with legislators. The same will occur with President Clinton's plan as he realizes he is not the heavyweight he thought he was when it comes to wheeling and dealing on Capital Hill.

Third, ***strategy*** — While those of us who have vested interest in health reform are aware that this change will be a substantive evolutionary change and not a symbolic revolutionary change, it is important that physicians, organized and unorganized, have a strategy for providing input and providing leadership. Our strategy then should be one in which we are receptive to dialogue and are involved in the arena as advisors and policy formulators ourselves. We must persist in our efforts to develop opportunities for input, and let us not forget that criticism is information. Even if current health care problems are largely ones of perception, we always have room for improvement.

One word to those of you who have chosen to become specialists rather than primary care generalists — there is still a place for you in our new health system. Sure, we need more generalists, more primary physicians. However, it was not potential for increased income that caused many of us to specialize, but a scientific challenge and a desire to be the very best. Limiting and focusing our areas of expertise have allowed us to reach unparalleled heights of excellence in medicine. For example, we don't see heads of state or rich oil sultans, who can purchase health care anywhere in the world, going

anywhere but to the United States as they seek to be treated. This is to say that here in the US we have the best care in the world and we probably always will have. There will always be a need for specialists and subspecialists and high technology physicians. This is because we relish the fact that we provide the best care in the world. There will always be a Sputnik in health care. There will always be a place for those who desire to be the very best. There is a great need for generalists, but the generalists cannot run the high intensity equipment that the specialists operate today.

In conclusion, we are witnessing a period when the symbolism rampant amongst our American politicians on health reform threatens the very fabric of the best system in the world and fills our lives with anxiety, dread, and inertia. However, change will not come from a revolutionary reform, but it will evolve through a substantive trial and error approach if past history is used as an example for future change.

Specialization is not ended nor should it be. The States rank first in health care, not because of our wonderful generalists and primary care physicians, although they are essential components of the system, but we rank as tops in the world because of our specialists and high intensity of medical care. It is ludicrous for our politicians to threaten to withdraw support for subspecialty training. We cannot go back in time.

So loosen up physicians, the end is not as near as it sometimes seems. There is hope. There is opportunity. There is ample time for us to move toward making needed changes along with preserving those excellent advantages we have attained.

Jannice O. Aaron, MD

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An Invitation to ALL PHYSICIANS SPOUSES . . . to come and help celebrate the KMAA's 70th Anniversary



Gloria J. Griffin

The Kentucky Medical Association Alliance will celebrate its 70th Anniversary on September 19, 1993.

The KMA Alliance leadership realizes that to become a stronger and more effective organization, we must develop and coordinate several comprehensive programs for physician spouses during the year. This year Louisville will be the host city for the KMA Annual Meeting in September. The KMA Alliance will also meet for it's Fall Conference on September 27-28. Debbe Dedman and Carol Goodin, the Fall Conference chairmen, have planned two days of meetings and workshops. We encourage and invite all physician spouses, even if you're not currently a member, to participate in any or all of our sessions. If all physician spouses will just take this opportunity to attend, they will get a good overview of what the KMA Alliance currently is involved with in addressing issues of the 90s and the challenges of the 21st century.

KMAA registration and ALL meetings and workshops will be held in the Conference Theatre on the second floor of the Hyatt Hotel. The following meetings are open to ALL physician spouses:

- Monday afternoon — KMAA Board and County presentations
- Tuesday — Opening session of the KMA House of Delegates — the Immediate AKMA Past President will present the KMAA Alliance American Medical Association Education Research Foundation check to the University of Kentucky and University of Louisville Medical School Deans. Following this presentation, Workshops regarding Child Abuse/Domestic Violence, Teen Pregnancy/AIDS, Medical Malpractice/How to Cope will be presented during the day
- Tuesday and Wednesday — *McFund Boutique*

Stop by the KMAA Booth at the Convention Center to review the schedule for this meeting and to pick up material about the KMA Alliance.

In addition to our scheduled meetings, the KMAA Hospitality Suite will be open during scheduled times on Monday and Tuesday. This is a place you can come to meet old friends, make a new friend, enjoy some refreshments, or just rest your feet. The Hospitality Suite will be manned by the Jefferson County Medical Society Auxiliary. On Tuesday and Wednesday you may want to browse in the *McFund Boutique.* Proceeds from the *Boutique* will benefit the Ronald McDonald Houses in Lexington and Louisville and the Ephraim McDowell House in Danville.

Physician spouses have but one choice and that is to work side by side to support our Kentucky physicians. You can help us accomplish more by belonging to the KMA Alliance so we can unite with one voice for quality health care in communities across Kentucky.

We are encouraging all physicians and their spouses to attend the KEMPAC Dinner on Monday, September 27.

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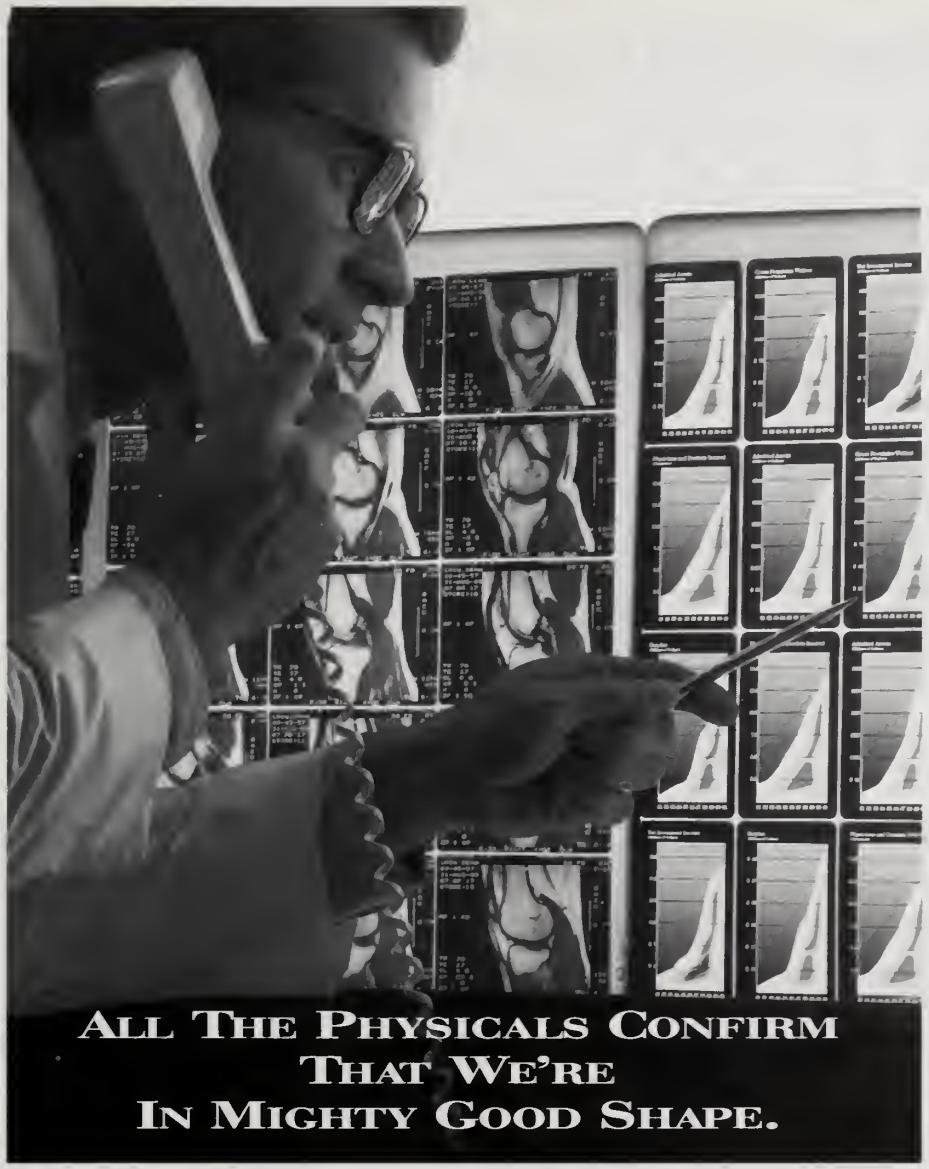
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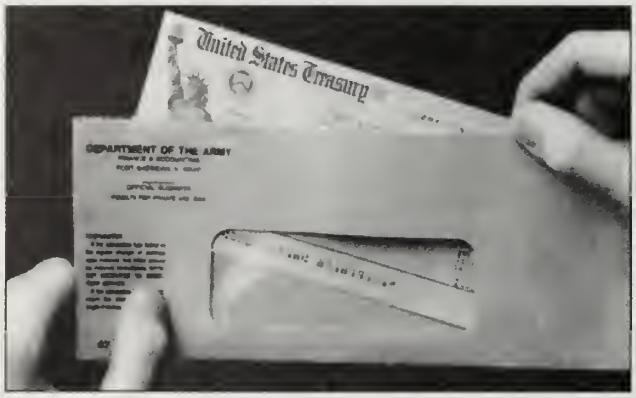
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Official Call
KMA Annual Meeting

To the officers and members of the component and county medical societies of the KMA.

Meeting Place

The Annual Meeting of KMA will convene on Tuesday, Wednesday, and Thursday, September 28, 29, & 30, at the Hyatt Regency Hotel and Commonwealth Convention Center, Louisville. The first General Session will be called to order at 8:30 AM, Tuesday.

The House of Delegates

The first regular meeting of the House of Delegates will convene at 9:00 AM, Monday, September 27, in the Regency Ballroom, located in the Hyatt Hotel. The second regular business meeting will begin at 7:00 PM, Wednesday, September 29, in the Regency Ballroom.

Registration

The Registration Desk, located outside the Regency Ballroom, 2nd Floor of the Hyatt Regency Hotel, will be open for Delegates at 7:30 AM, Monday, September 27, and at 6:00 PM, Wednesday, September 29. General registration will be held from 7:45 AM until 5:00 PM on Tuesday; 7:45 AM to 4:00 PM on Wednesday; and 7:45 AM to 1:00 PM on Thursday, at the General Registration Desk located in the lobby of the Commonwealth Convention Center.

KMA Officers 1992-93



William B. Monnig, MD
KMA President

On September 29, William B. Monnig, MD, Edgewood, will pass the leadership of the Kentucky Medical Association to Ardis D. Hoven, MD, Lexington.

Dr Monnig began his exemplary service to KMA in 1984 when he was elected Eighth District Trustee, a position he held until 1990. From 1987 until 1990, Dr Monnig also served as Chairman of the Board of Trustees, Chairman of the Executive Committee of the Board of Trustees, and as a member of the Quick Action Committee. In 1990 he was elected Vice President of KMA. His commitment to KMA has been apparent through his many committee memberships, with current obligations to the Scientific Program, PLI, Medical Insurance & Prepayment Plans and Physician-Attorney Liaison Committees.

A native of Ohio, Dr Monnig earned a medical degree in 1969 from the University of Cincinnati. He completed an internal medicine internship at the University of Illinois in 1970, followed by completion of a surgical residency in 1971 and a urology residency in 1974 at the University of Cincinnati. Dr Monnig is a board certified urologist and an assistant clinical professor in the Department of Surgery at the University of Cincinnati.

Dr Monnig has served KMA with strong and dedicated leadership during a very challenging year for physicians. The Association recognizes and appreciates his many contributions to the profession.



Ardis D. Hoven, MD
President-Elect

Ardis D. Hoven, MD, Lexington, will be installed as President of the Kentucky Medical Association at the President's Luncheon on Wednesday, September 29. In so doing, she will hold the distinction of being the first woman President of the Association.

Dr Hoven has been dedicated and effective in her contributions to KMA through extensive service. Membership on numerous committees and the chairmanship of several have established Dr Hoven as a very knowledgeable member of the Board of Trustees. She also is the first woman ever to be elected to the KMA Board. She has chaired the Ad Hoc Committee on the Development of AIDS Guidelines, Committee on Medicare and Other Governmental Medical Programs, and from 1987 to present has chaired the Committee on Community and Rural Health. Dr Hoven also currently serves on the Scientific Program, State Legislative Activities Quick Action, and Professional Liability Insurance Committees, and is an AMA Alternate Delegate. In 1991 she was recipient of KMA's Educational Achievement Award.

A native of Cincinnati, Ohio, Dr Hoven received a medical degree from the University of Kentucky in 1970. Her postgraduate training was accomplished at the University of North Carolina-Chapel Hill. She interned there in 1970-71, completed a residency in internal medicine in 1973, and accomplished a fellowship in infectious diseases in 1973-75.



Vice-President
David C. Liebschutz, MD
Danville

Dr Liebschutz is a surgeon in Danville and a 1968 graduate of the University of Louisville School of Medicine. He served KMA as an Alternate Trustee from 1980 to 1986 and Trustee from 1986 to 1992. He is a member of the Professional Liability Insurance Committee, a fellow of the American College of Surgeons, and has served several terms as Governor of the Kentucky Chapter of the American College of Surgeons.



Secretary-Treasurer
William P. VonderHaar, MD
Louisville

A family practitioner, Dr VonderHaar has served on the Interspecialty Council, Professional Education Committee, and as a Delegate for Jefferson County for several terms. He currently serves on the State Legislative Activities, Continuing Medical Education and Professional Liability Insurance Committees. He is a charter fellow of the American College of Family Physicians and a member of the American Academy of Family Physicians. A recipient of KMA's Educational Achievement Award in 1988, Dr VonderHaar is a 1956 graduate of the University of Louisville School of Medicine.



Speaker of the House
Danny M. Clark, MD
Somerset

Dr Clark is an OB-GYN from Somerset and a 1962 graduate of the University of Cincinnati College of Medicine. He served KMA as Delegate from 1974-1980; 12th District Alternate Trustee from 1974-1980; 12th District Trustee from 1980-86; and Vice Speaker of the House from 1986-1989. Dr Clark is a member of the Committee on Maternal and Child Health and a fellow of the American College of Obstetricians and Gynecologists.



Vice Speaker of the House
C. Kenneth Peters, MD
Louisville

Dr Peters, a family practitioner, has served KMA as KEMPAC chairman, on the Legislative Committee 15 years, and has been a KMA Delegate 21 years. He is a past president of the Jefferson County Medical Society, a Charter Fellow of the American Academy of Family Practitioners, and a member of the Jefferson County Academy of Family Practitioners. Dr Peters is a 1960 graduate of the University of Louisville School of Medicine.

KMA Delegates to AMA



Donald C. Barton, MD
Carbin

Dr Barton, a family practitioner, was elected AMA Delegate in 1984. A past Chairman of the KMA Board of Trustees and past President of the Association, Dr Barton served as KMA Delegate from 1977-79 and AMA Alternate Delegate in 1983. He is past President of the Whitley County Medical Society; past chairman of the KEMPAC Board; and was 15th District KMA Trustee from 1978-84. Dr Barton, a 1960 graduate of the University of Louisville School of Medicine, chairs the Committee on National Legislative Activities and serves on the State Legislative Activities Committee.



Wally O. Montgomery, MD
Paducah

Dr Montgomery, a general surgeon, was elected AMA Delegate in 1988. He served KMA as Trustee for several years, as Vice-President, President-Elect, President, Alternate AMA Delegate, KEMPAC Chairman, and on numerous committees. He chairs the State Legislative Committee and Committee on PLI, and is a member of the National Legislative Committee. A 1962 graduate of the U of L School of Medicine, Dr Montgomery is a past KY Governor and Past President of the Kentucky Chapter of the American College of Surgeons and a diplomate of the American Board of Surgery.



Harold L. Bushey, MD
Barbourville

Dr Bushey was elected an AMA Delegate in 1989, having previously served as a KMA Delegate for 6 years; Alternate Trustee 1968-1972; 15th District Trustee 1972-1978; and Board Chairman of KEMPAC. He has served on numerous KMA committees. A 1954 graduate of Rochester Medical School, Rochester, NY, Dr Bushey is an internist. He is a member of the Southern Medical Association and a past secretary of the Knox County Medical Society.



Robert R. Goodin, MD
Louisville

Dr Goodin, an internist, was elected as AMA Alternate Delegate in 1987 and served consecutive terms until his election as a Delegate in 1991. He has served KMA on numerous committees and is currently chairman of the Physician Manpower Committee and a member of the CME Committee. Dr Goodin earned his medical degree in 1964 from the University of Louisville School of Medicine. He is a fellow of the American College of Physicians and the American College of Cardiology.

Journal Editors

A. Evan Overstreet, MD, Editor
Louisville

Dr Overstreet served on the Editorial Board for more than 6 years before becoming Editor of *The Journal* in September 1977. An internist, Dr Overstreet is a 1955 graduate of the University of Louisville School of Medicine. He is a member of the American Society of Internal Medicine, the American College of Physicians, the Transylvania Medical Society, and former President of the Louisville Society of Internists.

Daniel W. Varga, MD
Louisville

Dr Varga, an internist, joined *The Journal* in 1990 as Scientific Editor. A 1984 graduate of the University of Louisville School of Medicine, Dr Varga has served as an Alternate Delegate to the KMA House of Delegates. He is a diplomate of the American Board of Internal Medicine and a member of the American Association for the Advancement of Science, American College of Physicians, and the Southern Medical Association.

Stephen Z. Smith, MD
Louisville

Dr Smith has served as Assistant Scientific Editor for *The Journal* since 1977. He also serves as book review author. A dermatologist, Dr Smith is a 1971 graduate of Johns Hopkins University School of Medicine. He is a member of the KMA Claims and Utilization Review Committee, the American Academy of Dermatology, and the American Medical Association.

Milton F. Miller, MD
Louisville

Dr Miller is Associate Clinical Professor of Medicine at the University of Louisville School of Medicine. An internist, Dr Miller has served as Assistant Editor of *The Journal* since 1976, has been active in the Jefferson County Medical Society, and is a former President of the medical staff at Methodist Evangelical Hospital. He is a 1954 graduate of the University of Louisville School of Medicine.

Martha Keeney Heyburn, MD
Louisville

Dr Heyburn joined *The Journal* in 1986 as an Assistant Editor. An ophthalmologist, Dr Heyburn is a 1980 graduate of the University of Louisville School of Medicine. She has served the Jefferson County Medical Society as an Alternate Delegate to KMA, is a member of the American Academy of Ophthalmology, the American Medical Association, and has been a member of KMA since 1981.

Jannice O. Aaron, MD
Louisville

Dr Aaron joined *The Journal* in 1990 as an Assistant Editor. A radiologist, Dr Aaron is a 1977 graduate of the University of Louisville School of Medicine. She served KMA as a Delegate from Adair County in 1985-86 and Jefferson County in 1990. A Past President of the Greater Louisville Radiological Society, she is a member of several professional organizations and a diplomate of the American College of Radiology and the American Society of Neuroradiology.

William F. Hoagland, MD
Louisville

Dr Hoagland joined *The Journal* in 1991 as an Assistant Editor. A surgeon, Dr Hoagland is a 1983 graduate of the University of Louisville School of Medicine and has been active in the Jefferson County Medical Society. Dr Hoagland is a member of several professional organizations including the American College of Surgeons.

KMA District Trustees



Harry W. Carloss, MD
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Fifth District





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Second District





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Sixth District





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Eighth District





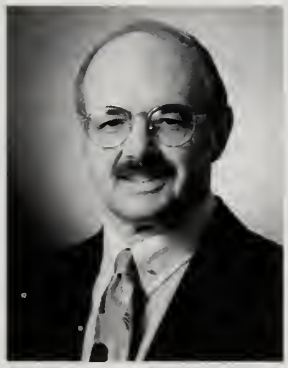
Don R. Stephens, MD
Ninth District





Charles T. Watson, MD
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Russell L. Travis, MD
Tenth District





E. D. Roberts, MD
Fourteenth District





William H. Mitchell, MD
Eleventh District





Paul R. Smith, MD
Fifteenth District





Scott B. Scutchfield, MD
Twelfth District



DIAGNOSIS & MANAGEMENT: SPECIAL ISSUES

KMA Delegates

Adair
Allen
John M. Hall, MD, Scottsville
Anderson
Patrick A. Sheridan, MD, Lawrenceburg
Ballard
Barren
Ray A. Gibson, MD, Glasgow
Morris David Moss, MD, Glasgow
Bath
Robin A. Byron, MD, Owingsville
Bell
Bourbon
James L. Ferrell, MD, Paris
Boyd
Kenneth R. Hauswald, MD, Ashland
Howard B. McWhorter, MD, Ashland
Maurice J. Oakley, MD, Ashland
Susan H. Prasher, MD, Ashland
Boyle
Arthur K. Rivard, MD, Danville
Scott B. Scutchfield, MD, Danville
Bracken
Breathitt
Breckinridge
James G. Sills, MD, Hardinsburg
Bullitt
Butler
Calloway
Carlisle
Glenn E. Hogancamp, MD, Bardwell
Carroll
Frank F. Palmer, MD, Carrollton
Carter
Casey
Lewis E. Wesley, MD, Liberty
Clark
Daniel Alan Ewen, MD, Winchester
Clay
Ira F. Wheeler, MD, Manchester
Clinton
Carol B. Peddicord, MD, Albany
Crittenden
Cumberland
Daviess
Jack C. Blackstone, Jr, MD, Owensboro
Gerald G. Edds, MD, Owensboro
William C. Harrison, MD, Owensboro
Christopher J. Havelda, MD, Owensboro
Philip B. Hurley, MD, Owensboro
William L. Tyler, III, MD, Owensboro
Edmonson
Omkar N. Bhatt, MD, Brownsville
Elliott
Estill
John A. Patterson, MD, Irvine
Fayette
James W. Baker, MD, Lexington
James R. Bean, MD, Lexington
John V. Borders, MD, Lexington
John W. Collins, MD, Lexington
W. Lisle Dalton, MD, Lexington
Elvis S. Donaldson, Jr, MD, Lexington
Richard D. Floyd, IV, MD, Lexington
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W. Jeffrey Foxx, MD, Lexington
Bill H. Harris, MD, Lexington
Dennis B. Kelly, MD, Lexington
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Andrew M. Moore, II, MD, Lexington
Preston Nunnelley, Jr, MD, Lexington
Barbara A. Phillips, MD, Lexington
John W. Poundstone, MD, Lexington
Andrew R. Pulito, MD, Lexington
Barry N. Purdom, MD, Lexington
Glenn R. Shearer, MD, Lexington
Thomas K. Slabaugh, MD, Lexington
David B. Stevens, MD, Lexington
John D. Stewart, MD, Lexington
John Robert White, MD, Lexington
Emery A. Wilson, MD, Lexington
Fleming
Glenn R. Womack, MD, Flemingsburg
Floyd
Nicholas R. Jurich, MD, Prestonsburg
Raghu R. Sundaram, MD, Martin
Franklin
John M. Patterson, MD, Frankfort
Jeffrey L. Rice, MD, Frankfort
Jan J. Weisberg, MD, Frankfort
Fulton
Gallatin
Benjamin Kutnicki, MD, Warsaw
Garrard
Paul J. Sides, MD, Lancaster
Grant
Graves
Charles E. Bea, MD, Mayfield
Grayson
Ray A. Cave, MD, Leitchfield
Green
Greenup
Manuel S. Garcia, MD, Ashland
John O. Jones, MD, Flatwoods
Hancock
David K. L. Tan, MD, Lewisport
Hardin-Larue
Vivian H. Bland, MD, Elizabethtown
David Dao, MD, Elizabethtown
Amarjit M. Desai, MD, Elizabethtown
Lucian Yann Moreman, II, MD, Elizabethtown
Jeffrey B. Richardson, MD, Elizabethtown
Harlan
F. Andrew Morfesis, MD, Harlan
Kenneth W. Smith, MD, Harlan
Harrison
Hart
George B. Boeckmann, MD, Horse Cave
Henderson
Thomas M. Gadient, MD, Henderson
Frank K. Sewell, Jr, MD, Henderson
Rogelio A. Silva, MD, Henderson
Hickman
Bruce C. Smith, MD, Clinton
Hopkins
Wallace R. Alexander, MD, Madisonville
James M. Bowles, MD, Madisonville
Uday Dave, MD, Madisonville
Mohan K, Rao, MD, Madisonville
Rodger J. Zwemer, Jr, MD, Madisonville
Jackson
Jefferson
Jannice O. Aaron, MD, Louisville
David T. Allen, MD, Louisville
Arnold M. Belker, MD, Louisville
Susan M. Berberich, MD, Louisville
S. J. Bertolone, Jr, MD, Louisville
Charles J. Bisig, Jr, MD, Louisville
David H. Bizot, MD, Louisville
Harold W. Blevins, MD, Louisville
Susan G. Bornstein, MD, Louisville
Mark H. Bronner, MD, Louisville
William C. Buschemeyer, Jr, MD, Louisville
David E. Bybee, MD, Louisville
Peter C. Campbell, MD, Louisville
Gregory J. Ciliberti, MD, Louisville
Stuart P. Cohen, MD, Louisville
J. William Comer, MD, Louisville
Peter M. Conway, MD, Louisville
Robert Craig DeWeese, MD, Louisville
John H. Doyle, MD, Louisville
Rudy J. Ellis, Jr, MD, Louisville
Marjorie R. Fitzgerald, MD, Louisville
Larry D. Florman, MD, Louisville
Beverly M. Gaines, MD, Louisville
Toni Michelle Ganzel, MD, Louisville
Henry D. Garretson, MD, Louisville
Katherine P. Garrison, MD, Louisville
Darius Ghazi, MD, Louisville
Harold D. Haller, MD, Louisville
Jayne L. Hollander, MD, Louisville
Walter I. Hume, Jr, MD, Louisville
Barbara Sue Isaacs, MD, Louisville
Clifford V. Jennings, MD, Louisville
John Jurige, Jr, MD, Louisville
Arthur H. Keeney, MD, Louisville
Donald R. Kmetz, MD, Louisville
Robert W. Linker, III, MD, Louisville
Laszlo J. K. Makk, MD, Louisville
Martha T. McCoy, MD, Louisville
Gordon T. McMurry, MD, Louisville
Robert L. McQuady, Jr, MD, Louisville
Frank B. Miller, MD, Louisville
Catherine Newton, MD, Louisville
Robert L. Nold, MD, Louisville
Charles R. Oberst, MD, Louisville
Hobert L. Pence, MD, Louisville
James E. Redmon, MD, Louisville
K. Thomas Reichard, MD, Louisville
William M. Renda, MD, Louisville
Sheldon B. Schiller, MD, Louisville
George Randolph Schrodt, MD, Louisville
George R. Schrodt, Jr, MD, Louisville
Edward L. Scofield, MD, Louisville
Robert W. Shaw, III, MD, Louisville
Kerry L. Short, MD, Louisville
Lynn T. Simon, MD, Louisville
Wm. C. Templeton, III, MD, Louisville
Rebecca Terry, MD, Louisville

Edward D. Tillett, MD, Louisville
Daniel W. Varga, MD, Louisville
Gary C. Vitale, MD, Louisville
Thomas R. Watson, MD, Louisville
Samuel D. Weakley, MD, Louisville
Barbara Weakley-Jones, MD, Louisville
A. Franklin White, Jr, MD, Louisville
Fred A. Williams Jr, MD, Louisville
C. Milton Young, III, MD, Louisville
Kenneth N. Zegart, MD, Louisville

Jessamine
Phyllis J. Corbitt, MD, Wilmore

Johnson

Knott
W. Grady Stumbo, MD, Hindman

Knox
William S. Black, MD, Barbourville

Laurel
David W. Douglas, MD, London

Lawrence

Lee
James B. Noble, MD, Beattyville

Leslie

Letcher
Van S. Breeding, MD, Whitesburg

Lewis
Karl H. Smith, DO, Vanceburg

Lincoln

Livingston
Stephen Burkhart, MD, Salem

Logan

Madison

Magoffin

Marion
Frederick A. Dorroh, MD, Lebanon

Marshall
H. W. Ford, MD, Benton

Martin

Mason
Kelly Moss, MD, Maysville

McCracken
Harry W. Carloss, MD, Paducah
Keith H. Crawford, MD, Paducah
Charles K. Davis, MD, Paducah
Larry C. Franks, MD, Paducah
Stephanie R. Hatfield, MD, Paducah
John D. Noonan, MD, Paducah

McCreary

McLean

Meade
Raymond L. Mathis, DO, Brandenburg

Menifee

Mercer

Metcalfe
Lawrence P. Emberton, MD, Edmonton

Monroe
James E. Carter, MD, Tompkinsville

Montgomery

Morgan
George R. Bellamy, MD, West Liberty

Muhlenberg
James S. Brashear, MD, Central City

Nelson

Nicholas
Geoffrey A. Peters, MD, Carlisle

Northern Kentucky
Gordon W. Air, MD, Crestview Hills
Robert L. Baker, Jr, MD, Florence
Elbert D. Baldridge, Jr, MD, Covington
Thomas E. Bunnell, MD, Erlanger
James L. Evans, III, MD, Fort Thomas
Joseph C. Martin, MD, Erlanger
Ross McHenry, MD, Covington
George E. Miller, MD, Crescent Springs
Theodore H. Miller, MD, Edgewood
Michelle M. Murray, MD, Alexandria
Michael L. Robinson, MD, Edgewood
Marguerite S. Schabell, MD, Florence
B. Robert Schwartz, MD, Edgewood
Steven M. Woodruff, MD, Florence

Ohio

Owen
O. Abbett Cull, MD, Owenton

Owsley

Pendelton
Robert L. McKenney, MD, Falmouth

Pennyrile
Emmanuel J. Battah, MD, Hopkinsville
Hank Bell, Jr, MD, Elkton
Ralph L. Cash, Jr, MD, Princeton
Harry J. Dempsey, MD, Hopkinsville
Steve Hiland, MD, Eddyville
J. Nicholas Terhune, MD, Hopkinsville

Perry
Mitchell Wicker, Jr, MD, Hazard

Pike
Dennis H. Halbert, MD, Pikeville
Charles G. Nichols, MD, Pikeville
Elster D. Roberts, MD, Pikeville

Powell
Charles G. Noss, MD, Stanton

Pulaski
Donald E. Brown, MD, Somerset
Danny M. Clark, MD, Somerset
Joseph G. Weigel, MD, Somerset

Robertson

Rockcastle
William D. Dooley, MD, Mount Vernon

Rowan
Marc L. Holbrook, MD, Lexington

Russell
H. Michael Oghia, MD, Russell Springs

Scott
R. Kendall Brown, MD, Georgetown

Simpson

Spencer
Thomas C. Crain, MD, Taylorsville

Taylor
Eugene H. Shively, MD, Campbellsville

Tri-County
Harold F. Funke, MD, Crestwood
M. Brooks Jackson, II, MD, Shelbyville
Steven D. White, MD, Campbellsburg

Trimble
Roderick H. MacGregor, MD, Bedford

Union
Wallas N. Bell, MD, Morganfield

Warren
James F. Beattie, Jr, MD, Bowling Green
Joe T. Davis, MD, Bowling Green
Stuart G. Yeoman, MD, Bowling Green

Washington
Suk K. Koh, MD, Springfield

Wayne
James K. Phillips, Jr, MD, Monticello

Webster

Whitley
Raymond J. Monaco, Jr, MD, Corbin
Jagdish S. Patil, MD, Corbin

Wolfe
Wallace Past, Jr, MD, Campton

Woodford
Norman S. Fisher, MD, Midway

KMA Hospital Medical Staff Section
William D. Pratt, MD, London

KMA Resident Physicians Section
Robin M. Floyd, MD, Madisonville

KMA Student Section
Michael Dragan, UK, Lexington
William C. Thornbury, Jr, UL, Louisville

DIAGNOSIS & MANAGEMENT: SPECIAL ISSUES

Elections

Nominating Committee to Meet Monday, September 27

The KMA Nominating Committee will hold an open meeting at the close of the first meeting of the House of Delegates, Monday, September 27, in the Regency Ballroom of the Hyatt Regency Hotel. Any KMA member may confer with the Committee during this meeting.

The report of the Nominating Committee will be posted in the general assembly hall at the conclusion of the first general session, Tuesday morning, September 28.

Nominations may be made from the floor during the second meeting of the House of Delegates, Wednesday evening, September 29, in the Regency Ballroom. The House will vote on the nominees at this meeting.

Members of this Committee are: Joseph G. Weigel, MD, Somerset, Chairman; John V. Borders, MD, Lexington; William C. Harrison, MD, Owensboro; John M. Karibo, MD; Louisville; and Frank K. Sewell, Jr, MD, Henderson.

Nominations should be sent before the Annual Meeting to the KMA Headquarters Office, Attention, Nominating Committee.

House to Elect New Officers During Annual Meeting

KMA officers for the 1993-94 Association year will be elected by the House of Delegates at the close of its final meeting, Wednesday evening, September 29. Officers to be elected from the state-at-large are:

Office	Year
President-Elect	1 Year
Vice President	1 Year
Secretary-Treasurer	3 Years
*William P. VonderHaar, MD Louisville	
Delegates to AMA	2 Years
*Donald C. Barton, MD Corbin	
*Harold L. Bushey, MD Barbourville	
Alternate Delegates to the AMA	2 Years
*Donald J. Swikert, MD Florence	
*J. Gregory Cooper, MD Cynthiana	

*Incumbent

Election of Trustees and Alternate Trustees

The House of Delegates will elect five District Trustees and six Alternate Trustees at its second regular meeting, Wednesday, September 29. Nominations will be made by the Delegates from the electing Districts, at a meeting following the first meeting of the House on Monday, September 27.

The Nominating Committee will report at the close of the first scientific session on Tuesday, September 28. Further nominations may be made from the floor at the final meeting of the House on Wednesday evening, September 29. All nominations are considered and acted upon by the Delegates at this final meeting.

Districts electing Trustees for 3-year terms are: 5th District (incumbent, Joseph E. Kutz, MD, Louisville); 6th District (incumbent, Jerry W. Martin, MD, Bowling Green); 8th District (incumbent, Mark F. Pelstring, MD, Covington); 11th District (incumbent, William H. Mitchell, MD, Richmond); and 15th District (incumbent, Paul R. Smith, MD, London).

Trustees in the 5th, 8th, and 15th Districts are eligible for reelection, while the Trustees in the 6th and 11th Districts have served two consecutive terms and are not eligible for reelection.

Districts electing Alternate Trustees are the same as those electing Trustees. Incumbents are: 5th District, Larry J. Wilson, MD, Louisville; 6th District, John D. Gover, MD, Bowling Green; 8th District, John D. Ammon, MD, Florence; 11th District, G. Irene Minor, MD, Berea; and 15th District, Roger A. Acosta, MD, Barbourville. All Alternate Trustees are eligible for reelection.

In addition, there is a vacancy in the 4th District, and an Alternate needs to be elected to fill the two years remaining in that term.

Reference Committee Activity

Speakers Danny M. Clark, MD, Somerset, and C. Kenneth Peters, MD, Louisville, will assign all officers' and committees' reports and Resolutions to one of six Reference Committees at the first meeting of the KMA House of Delegates at 9:00 AM, Monday, September 27. A brief session for Reference Committee Chairmen will be held at 11:00 AM Monday in the Derby Suite, located in the Hyatt Hotel. Any KMA member wishing to testify on any Resolution or report is urged to be present for the Reference Committee meetings which will be held at noon Monday, September 27, on the first floor of the Hyatt Hotel. These open sessions will last at least one hour in order for all who wish to speak to be heard. Following the open hearings, the Committees will go into executive sessions to study the reports, review the testimony, and write their reports to the House.

The Committees' recommendations will be presented at the final meeting of the House, Wednesday evening, September 29, in the Regency Ballroom, Hyatt Hotel.

Appointments to Reference Committees and Credentials Committee and Tellers are now being finalized by the Speakers.

If your society has not yet submitted the name of your Delegate(s) to the Headquarters Office, you should do so immediately, as only those names recorded in the office can be considered for appointment to one of the Reference Committees and be listed as official county representatives.

A complete listing of members who will be serving on the six Reference Committees and the location of the Reference Committee meetings will be published in the September issue of the KMA *Journal*.

Anyone desiring names of Reference Committee members before the September issue is published should contact the Headquarters Office.

Make Your Reservations Now

It is important that you begin to make your room reservations as soon as possible for the KMA Annual Meeting, September 27-30. The Hyatt Regency Louisville will be the Headquarters Hotel (Phone 502/587-3434). In making your reservations, remember the first House of Delegates meeting will be Monday, September 27. Be sure and identify yourself as a KMA meeting attendee to receive the special convention rate — Single — $71/Double — $81.

Annual Meeting Special Features



1993 Annual Meeting Honors Past President William O. Roberts, MD

The 1993 Annual Meeting of the Kentucky Medical Association will be officially titled "The William Owen Roberts Meeting" in remembrance of the 1913 President of the Association. The tradition of honoring a past president of KMA and other distinguished physicians originated with the 1935 Annual Meeting. Eugene H. Conner, MD, Louisville, KMA Historian, has written a biography on Dr Roberts that begins on page 353.

Scientific Sessions are scheduled for September 28 and 29 at the Commonwealth Convention Center in Louisville. The theme for the 1993 scientific session is "Diagnosis and Management: Special Issues." Both the presentations and discussion periods will contribute to the continuing medical education of Kentucky's physicians.

Twenty-three Specialty Groups will hold meetings on September 28, 29 & 30. Beginning at 1:30 PM on Tuesday, 2:15 PM on Wednesday, and 9:00 AM on Thursday, they will be held in the meeting rooms located on the lower level of the Commonwealth Convention Center. Individual programs of specialty societies are listed in this issue. All general sessions will be held in the mornings. Specialty groups will meet all three days with no general sessions scheduled during these specialty group meetings. All KMA members are invited to attend any specialty meetings.

Scientific and Technical Exhibits will display new medical products, services, and techniques in the Exhibit Hall, located in the Commonwealth Convention Center, during the 1993 Annual Meeting. Members and guests are urged to take the opportunity to view products of interest at the 30-minute intermissions scheduled during each general and specialty session.

The KMA House of Delegates will meet twice during the Annual Meeting. The first meeting of the House will be held at 9:00 AM, Monday, September 27, in the Regency Ballroom located in the Hyatt Hotel. The final meeting will be held Wednesday, September 29, at 7:00 PM, also in the Regency Ballroom. Officers for the 1993-94 Associational year will be elected at the second meeting.

The President's Installation & Awards Luncheon will be held on Wednesday, September 29, in the Regency Ballroom located in the Hyatt Hotel. The luncheon will include the presentation of KMA awards and the installation of the 1993-94 President, Ardis D. Hoven, MD, Lexington.

Capsule Schedule of 1993 Annual Meeting

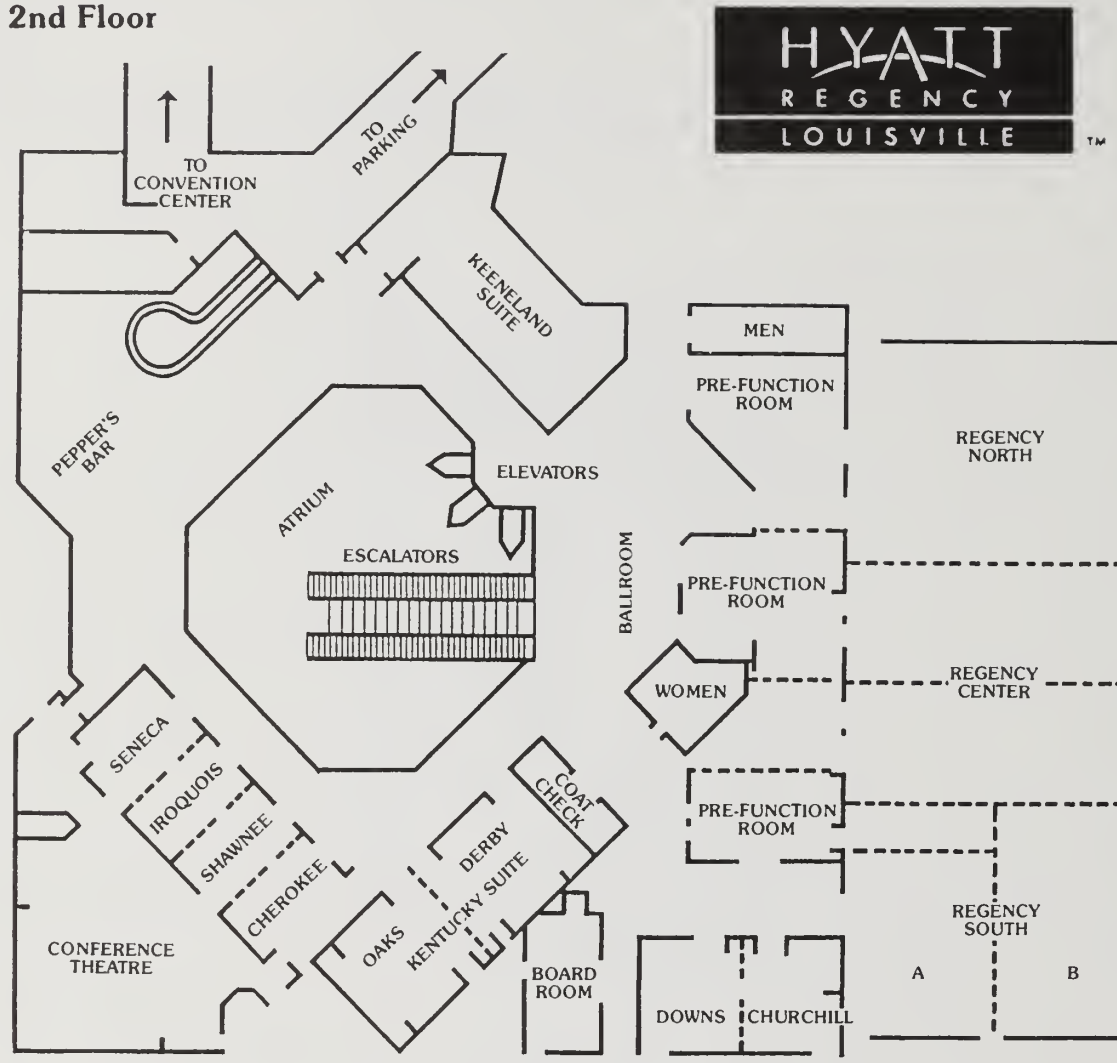
CC = Commonwealth Convention Center
HH = Hyatt Regency Hotel

	Sunday, September 26	
9:00 AM	KMA Executive Committee Meeting	Derby Room-HH
12:30 PM	KMA Board of Trustees Meeting & Lunch	Regency Ballroom South-HH
	Monday, September 27	
7:30 AM	Registration for House of Delegates	Outside Regency Ballroom-HH
7:30 AM	Continental Breakfast for House of Delegates hosted by JCMS	Regency Ballroom Foyer-HH
9:00 AM	First Meeting, KMA House of Delegates	Regency Ballroom North & Center-HH
10:00 AM	Alliance Committee Meetings	Conference Theatre-HH
10:30 AM	Trustee Districts Nominating Committees/KMA Nominating Committee	Regency Ballroom North & Center-HH
11:00 AM	Luncheon, Reference Committee Chairmen	Derby Room-HH
12:00 NOON	Reference Committee Meetings	Various Meeting Rooms-HH
1:00 PM	Alliance Fall Board Meeting	Conference Theatre-HH
6:00 PM	KEMPAC Reception & Dinner	Regency Ballroom-HH
	Tuesday, September 28	
7:00 AM	KEMPAC Board Breakfast Meeting	Regency Ballroom South-HH
7:00 AM	Maternal Mortality Committee Breakfast	Seneca-HH
7:45 AM	Registration	Registration Area-CC
8:00-9:00 AM	Reference Committee Report Signing	Churchill Downs-HH
8:15-9:00 AM	Free Coffee & Danish	Exhibit Hall-CC
8:30 AM	Opening Ceremonies, First Scientific Session	General Sessions Area-CC
12:00 NOON	Young Physicians Luncheon	Keeneland Suite-HH
12:00 NOON	Luncheon Meeting, Executive Committee & Reference Committee Chairmen	Kentucky Suite-HH
12:00 NOON	Alliance Luncheon	Regency Ballroom South-HH
1:00 PM	MSS/RPS Annual Meeting	Lower Level-CC
1:30 PM	Specialty Group Sessions . . . (Eight Specialty Groups will meet simultaneously at this time. Their programs begin on page 357)	Various Meeting Rooms-CC
	Wednesday, September 29	
7:45 AM	Registration	Registration Area-CC
8:15-9:00 AM	Free Coffee & Danish	Exhibit Hall-CC
8:30 AM	Second Scientific Session	General Sessions Area-CC
11:50 AM	President's Installation/Awards Luncheon	Regency Ballroom North & Center-HH
2:15 PM	Specialty Group Sessions . . . (Eight Specialty Groups will meet simultaneously at this time. Their programs begin on page 360)	Various Meeting Rooms-CC
3:00 PM	KMA Board of Trustees Meeting & Dinner	Regency Ballroom South-HH
7:00 PM	Second Meeting, KMA House of Delegates	Regency Ballroom North & Center-HH
	Thursday, September 30	
7:45 AM	Registration	Registration Area-CC
8:15-9:00 AM	Free Coffee & Danish	Exhibit Hall-CC
9:00 AM	Specialty Group Sessions . . . (Seven Specialty Groups will meet simultaneously at this time. Their programs begin on page 362)	Various Meeting Rooms-CC
12:00 NOON	KMA Board of Trustees Luncheon Meeting	Regency Ballroom South-HH

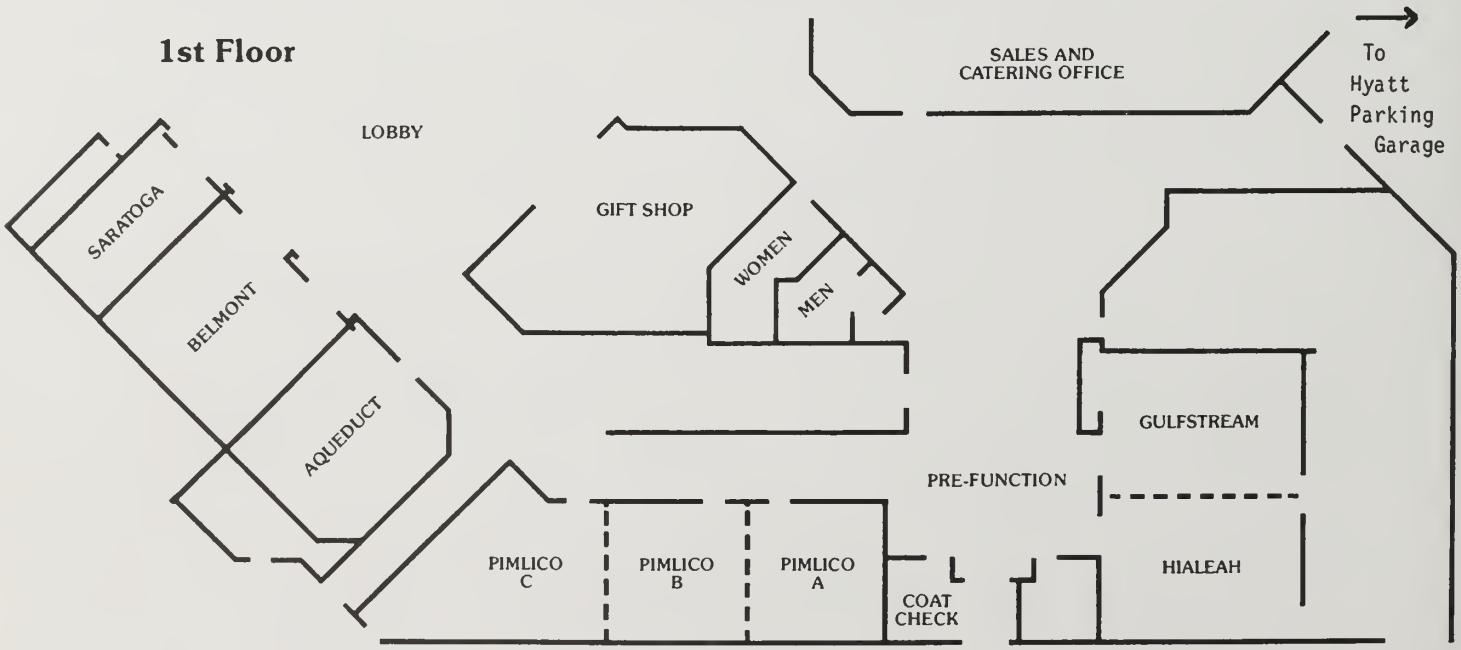
A 30-minute intermission has been scheduled during each Scientific Session and Specialty Group Session for visiting Exhibits.

HOTEL FUNCTION SPACE

2nd Floor



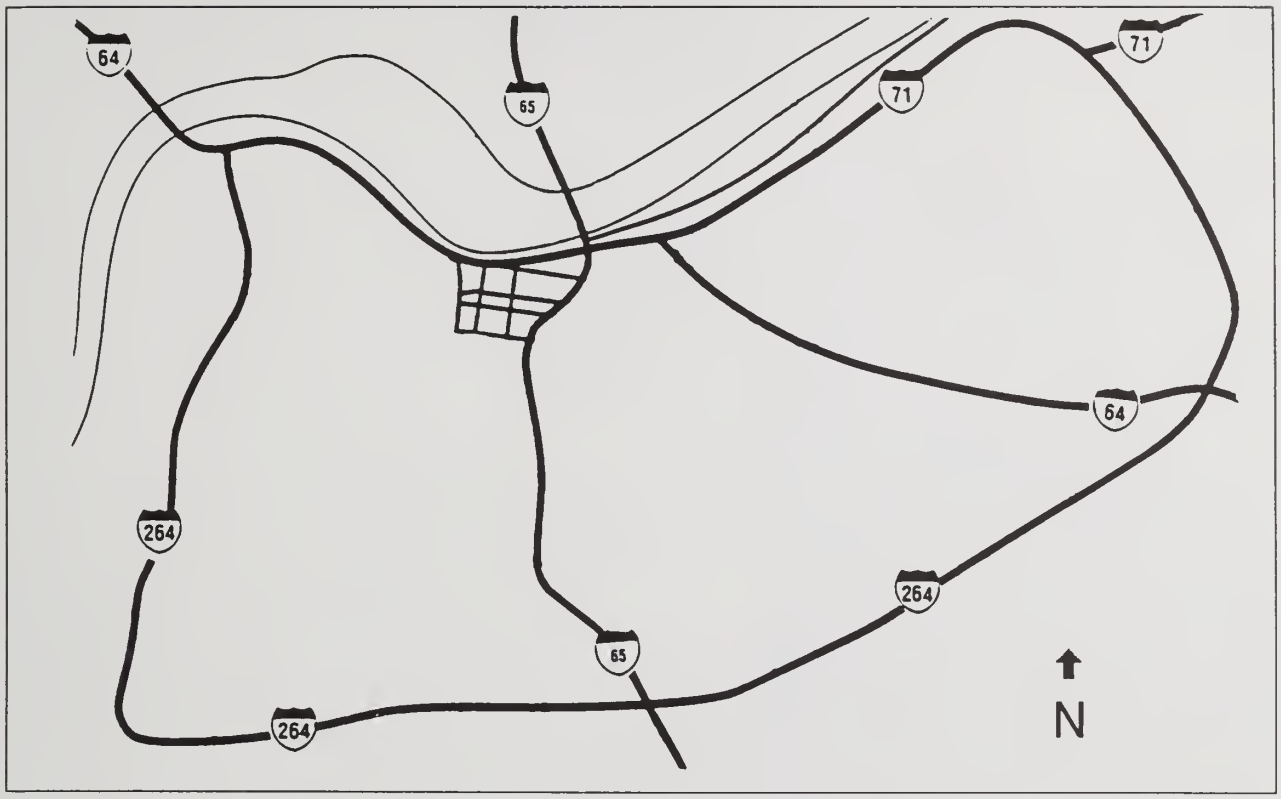
1st Floor



TEAR OUT MAPS

of Major Routes and Convenient Parking Locations in Downtown Louisville

TO REACH HYATT REGENCY/ COMMONWEALTH CONVENTION CENTER

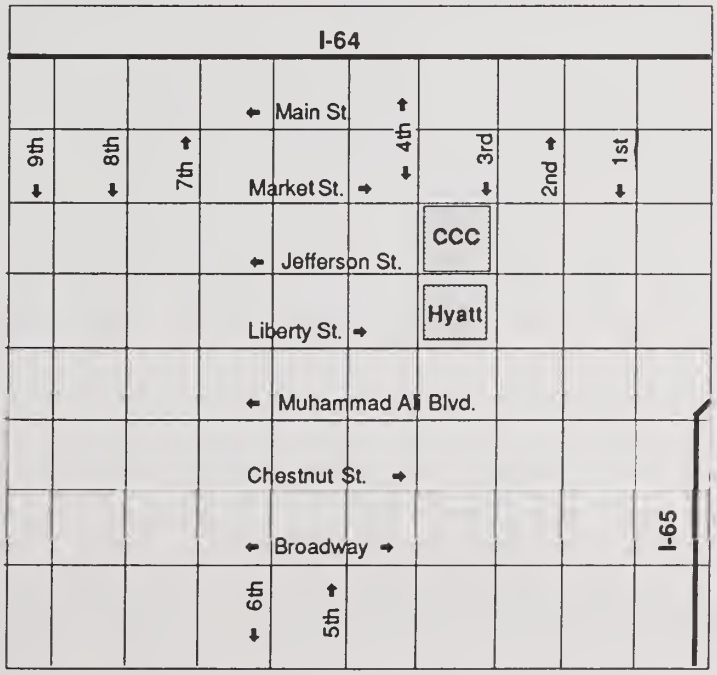


From I-64/1-71 Westbound:
Take 3rd St. exit, go south on 3rd, turn right on Jefferson.

From I-64 Eastbound:
Take 9th St. exit, go south on 9th, turn left on Market.

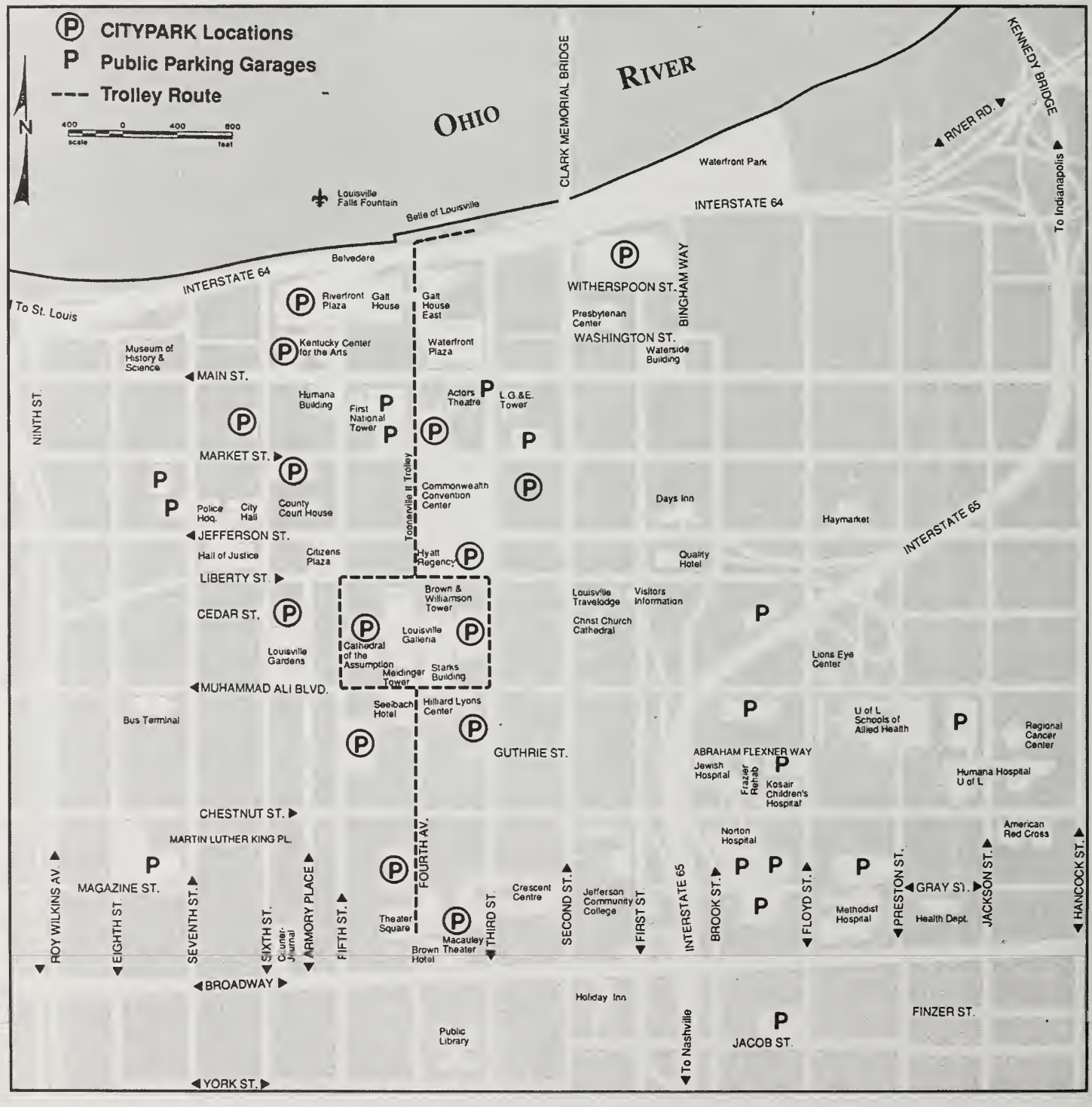
From I-65 Northbound:
Take Muhammad Ali Blvd. exit, go west on Muhammad Ali, turn right at 2nd St., turn left at Jefferson.

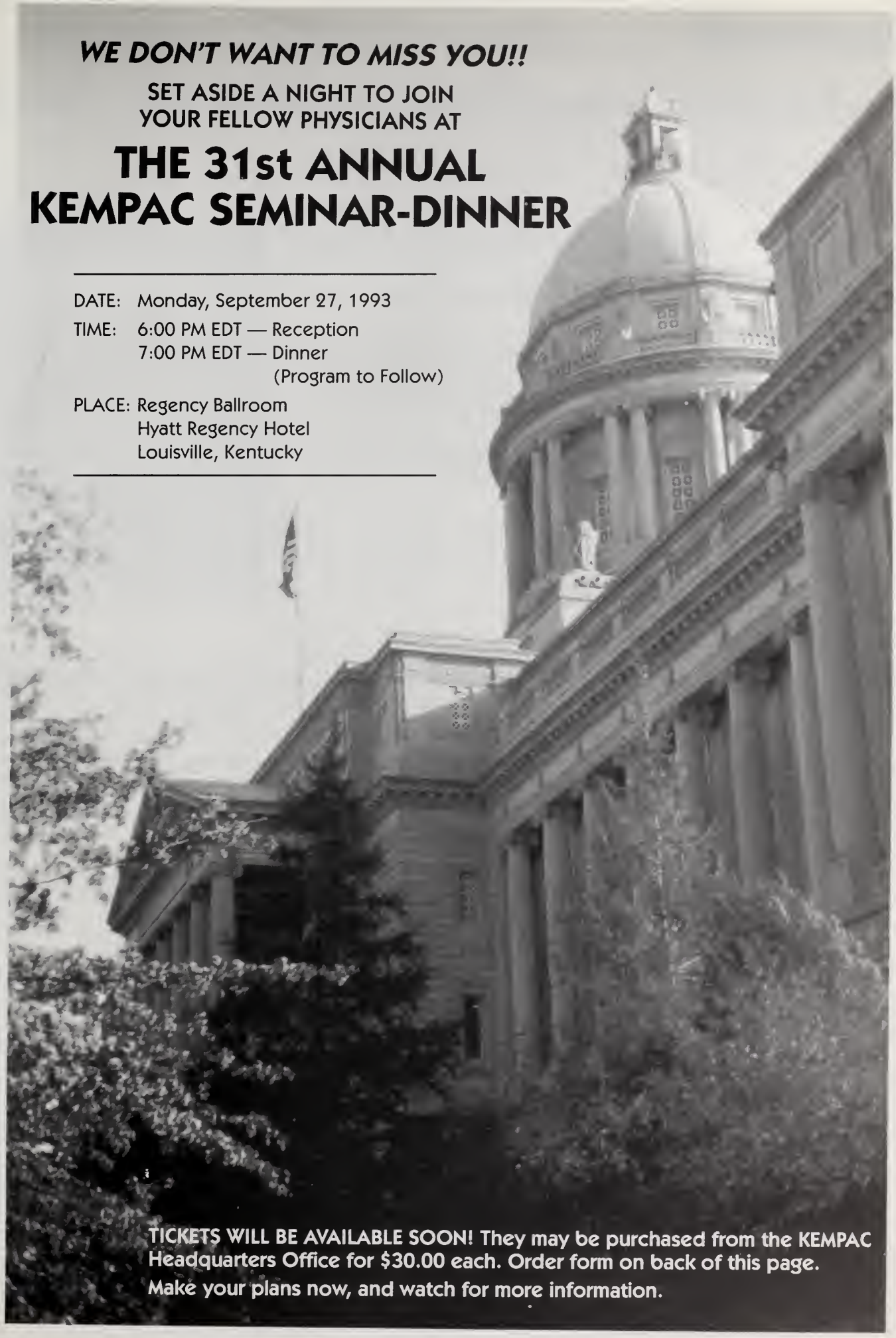
MAP INSET OF DOWNTOWN LOUISVILLE



DETAILED PARKING MAP ☛

PARKING MAP


CITYPARK Locations
Public Parking Garages
Trolley Route
N
400 0 400 800
scale feet
OHIO RIVER
CLARK MEMORIAL BRIDGE
KENNEDY BRIDGE
RIVER RD.
To Indianapolis
Waterfront Park
Louisville Falls Fountain
Belle of Louisville
INTERSTATE 64
Belvedere
To St. Louis
Riverfront Plaza
Galt House
Galt House East
Kentucky Center for the Arts
Waterfront Plaza
WITHERSPOON ST.
BINGHAM WAY
Presbyterian Center
WASHINGTON ST.
Waterside Building
Museum of History & Science
MAIN ST.
NINTH ST.
Humana Building
First National Tower
Actors Theatre
L.G.&E. Tower
MARKET ST.
Commonwealth Convention Center
Torrenville II Trolley
Days Inn
Haymarket
INTERSTATE 65
Police Hdq.
City Hall
County Court House
JEFFERSON ST.
Hall of Justice
Citizens Plaza
Hyatt Regency
Quality Hotel
LIBERTY ST.
Brown & Williamson Tower
Louisville Travelodge
Visitors Information
CEDAR ST.
Louisville Galleria
Christ Church Cathedral
Cathedral of the Assumption
Louisville Gardens
Meidinger Tower
Starks Building
Lions Eye Center
MUHAMMAD ALI BLVD.
Seelbach Hotel
Hilliard Lyons Center
Bus Terminal
U of L Schools of Allied Health
Regional Cancer Center
GUTHRIE ST.
ABRAHAM FLEXNER WAY
Jewish Hospital
Frazier Rehab
Kosair Children's Hospital
Humana Hospital U of L
CHESTNUT ST.
MARTIN LUTHER KING PL.
Norton Hospital
American Red Cross
ROY WILKINS AV.
MAGAZINE ST.
EIGHTH ST.
SEVENTH ST.
SIXTH ST.
Courier-Journal
ARMORY PLACE
FIFTH ST.
FOURTH AV.
Theater Square
Crescent Centre
SECOND ST.
Jefferson Community College
FIRST ST.
INTERSTATE 65
BROOK ST.
FLOYD ST.
Methodist Hospital
PRESTON ST.
GRAY ST.
JACKSON ST.
Health Dept.
HANCOCK ST.
THIRD ST.
Macauley Theater
Brown Hotel
BROADWAY
Holiday Inn
FINZER ST.
Public Library
To Nashville
JACOB ST.
YORK ST.



WE DON'T WANT TO MISS YOU!!

SET ASIDE A NIGHT TO JOIN
YOUR FELLOW PHYSICIANS AT

THE 31st ANNUAL KEMPAC SEMINAR-DINNER

DATE: Monday, September 27, 1993

TIME: 6:00 PM EDT — Reception
7:00 PM EDT — Dinner
(Program to Follow)

PLACE: Regency Ballroom
Hyatt Regency Hotel
Louisville, Kentucky

TICKETS WILL BE AVAILABLE SOON! They may be purchased from the KEMPAC Headquarters Office for $30.00 each. Order form on back of this page. Make your plans now, and watch for more information.

Medical Office and Clinic Staff Claims Prevention Seminar

Kentucky Medical Insurance Company will offer a special claims prevention seminar for medical office and clinic staff during the KMA Annual Meeting. The 1993 claims prevention seminar, developed specifically for the medical office/clinic staff member, is a fast-paced program entitled Promoting Positive Patient Perceptions. The program is designed to enhance your verbal and non-verbal communication skills.

The cost is $25 per office/clinic staff member employed by physicians insured by Kentucky Medical. For office/clinic staff whose physician employer is not insured by Kentucky Medical, the cost is $35 per person.

The seminar is scheduled from 9:00 to 11:00 AM on Wednesday, September 29, 1993, at the Hyatt Regency Hotel, Louisville. In order to register, please call Kentucky Medical Insurance Company either toll free at 800/467-1858, or in Louisville, 339-5771. Prompt registration is encouraged.

KEMPAC TICKETS ARE ON SALE NOW! They can be purchased from the KEMPAC Headquarters Office for $30.00 each. Make check payable to *KEMPAC* and mail to: KEMPAC, 301 N Hurstbourne Parkway, Suite 200, Louisville, Kentucky 40222

31st KEMPAC Seminar-Dinner — $30.00 per person.

NAME _____

ADDRESS _____

CITY _____

AMOUNT ENCLOSED $ _____ NO. OF TICKETS _____

GET YOUR TICKETS NOW AND YOU WILL BE SET!!!



William Owen Roberts, MD 1844-1921

William Owen Roberts, MD, assumed the presidency of the Kentucky State Medical Association at the Annual Meeting in Bowling Green, Kentucky, on September 2, 1913. At this time, there were US troops pursuing bandits in Mexico and grave political unrest in Europe. The entire western world seemed destined for war.

Ignoring such ominous signs of world unrest, W. O. Roberts focused on the accomplishments and functions of KMA. His address upon assuming office was entitled "The Progress of State Medicine, During the Past and Recent Years."[1] Therein he sketched the development of active county medical societies and how they revitalized the KMA during the latter years of the 19th century. It was in these regular monthly meetings that local practitioners participated in continuing their own medical education and discussed problems confronting the profession as well as the public whose life and health they were preserving. He commented upon how these local societies taught public health measures to Kentuckians through medical practitioners lecturing on communicable diseases and hygiene to local civic, church, and social groups. Physicians examining school children for evidence of threatening epidemic diseases also taught the children principles of hygiene and disease prevention.

On the teaching faculty of the University of Louisville Medical Department for nearly all of his professional lifetime, Dr Roberts was particularly proud of the attitude and assistance rendered by the KMA in establishing a single Class A medical school in Louisville by 1908.[2] Elevating standards of medical education ultimately resulted in raising the standards of medical care in Kentucky.

In his address, Dr Roberts lauded the *KMJ* and its editor, A. T. McCormack, MD, and his staff for the quality of papers as well as the fact that the *Journal* was self-sustaining through advertising.

At the time of the 1913 Annual Meeting the crusade against typhoid fever had gained momentum with the State Board of Health's immunizing Kentuckians throughout the state. The menace of communicable diseases still loomed large at this time, requiring quarantine and mass immunization to contain and eventually abolish such epidemics.

This carefully thought-out address of Dr Roberts indicates that some of the problems facing our profession at that time have yet to be solved today. We are still plagued by charlatans, irregular practitioners, unjustified malpractice suits, and a new viral venereal disease.

W. O. Roberts, the son of Ryland and Mary Roe Tompkins Roberts, was born on December 19, 1848, in Lynchburg, Virginia. Soon the family moved to Wytheville, Virginia, where they remained until W. O. was 16 years old when the family moved to Louisville. He may have completed his high school education in Louisville. His undergraduate education was at Washington and Lee University, Lexington, Virginia.

He received his MD from the University of Louisville Medical Department in 1870, listing David W. Yandell (1826-1898), MD, as his preceptor. After a brief exposure to practice, he enrolled at The Bellevue Hospital Medical College in New York City from which he received another MD the following year.[3]

By becoming an Assistant Demonstrator in Anatomy at his alma mater in Louisville soon after returning from his medical studies in New York City, he initiated a life-long association with the University of Louisville Medical Department.[4] Two years later he was promoted to Demonstrator in Anatomy.[5] Although

he claimed not to be a specialist, he began his orientation towards surgery as Instructor in Surgery in the Surgical Clinic at the University of Louisville Dispensary in 1874 during the Medical School summer session.[6] Soon he was invited to join the practice of David W. Yandell, MD, Professor of Clinical Surgery, University of Louisville Medical Department.

During the spring and summer of 1886, Dr Roberts traveled to the United Kingdom and Europe in quest of new medical knowledge and techniques. In three published letters he recounted his experiences and observations made in clinics in Edinborough, Glasgow, London, Paris, and Vienna.[7]

W. O. Roberts became an accomplished surgeon during his early professional association with Dr Yandell, and his medical faculty appointments reflected his increasing knowledge and skill. His published progression in the faculty at the University of Louisville Medical Department is as follows: Adjunct to the Professor of Surgery (1881-1884), Professor of Surgical Pathology and Operative Surgery (1885-1886), Professor of Principles and Practice of Surgery (1886-1906), Professor of Surgery and Clinical Surgery (1906-1912), Professor Emeritus of Surgery and Clinical Surgery (1912-1921).[8, 9] He became the successor to his father-in-law as Chief Surgeon of the Louisville & Nashville Railroad when Dr Yandell retired in 1892. Upon his own retirement in 1912, this appointment was passed to his son, David Yandell Roberts, MD.

Becoming professionally acquainted with Dr Yandell eventually led to his becoming personally acquainted with the Yandell family of three daughters and one son. Dr Roberts married one of the daughters, Maria. To this marriage was born three children, David Yandell Roberts, MD (UL, 1900), Ethyl Roberts (Mrs Charles Francis Wood) and John M. Y. Roberts. David Yandell Roberts, MD, became a surgeon and followed his father and grandfather as chief surgeon for the L&N RR.

Dr Roberts was always an active participant in KMA, the Medico-Chirurgical Society (President), and the Jefferson County Medical Society in Louisville. To specialty societies such as Southern Surgical and Gynecological Association (President, 1910) and the American Association of Railway Surgeons, he also accorded considerable attention and devotion.

A complete bibliography of his writings is not presently available, but five papers have been identified in addition to his KMA "President's Address." All are on surgical topics.[10] W. O. Roberts continually pursued his medical studies in the surgical clinics of Europe and in medical centers in the United States. He was widely known for his surgical skills. He was an able successor to the mantle of his mentor and father-in-law. An affable gentleman, he was generous with his talents to patients, friends, and colleagues. He cared for his patients at the City Hospital (teaching hospital of University of Louisville Medical Department), SS. Mary and Elizabeth, and Norton Memorial Infirmary.

Although never a candidate for public office, he did take an active part in civic affairs; his political party preference was Democrat. As to his religious convictions, he was a member of Calvary Episcopal Church. During his last years (he retired in 1918), he was blind and suffered from chronic interstitial nephritis which ultimately caused his death.[11, 12]

W. O. Roberts was a devoted physician whose leadership skills were expended for improvement in medical education, medical care, and medical society function. He was a compleat physician whose unselfish contributions to students, patients, and colleagues shall be recalled and his name honored at this memorial meeting.

Eugene H. Conner, MD
KMA Historian

Photo courtesy of University of Louisville Archives. Collected portraits of JCMS members, Standiford Studio. Ca 1920.

References

1. Roberts WO. The Progress of State Medicine, During the Past and Recent Years. *KMJ.* 1913;*11*:816–824.
2. Horine EF. A History of the Louisville Medical Institute and of the Establishment of the University of Louisville and its School of Medicine, 1833-1846. *Filson Club Hist Q.* 1933;*7*:132–147.
3. Seekamp A and Burlingame R, Editors. *Who's Who in Louisville.* The Louisville Press Club, Louisville Anzeiger Press. 1912;187.
4. *Polk's Medical Register & Directory of North America.* R. L. Polk & Co, Detroit, Baltimore & Chicago, 1910. p 783.
5. *36th Ann Announcement Med Dept UL, Session of 1872-73.* J. P. Morton & Co, Louisville, 1872, p. [2].
6. *38th Ann Announcement Med Dept UL, Session of 1874-75.* J. P. Morton & Co, Louisville, 1874, p. [2].
7. Roberts WO. [Letter to the editors]; *Am Pract & News.* 1886; *1* n.s. 410–415; 1886. *2* n.s. 56–58, 91–94.
8. Vide supra No 6, p. 7.
9. *45th Ann Announcement Med Dept UL; Session of 1881-82,* n.p., n.d. p. 2.
 49th Ann Announcement Med Dept UL; Session of 1885-86, J.P. Morton, Louisville, KY. 1885, p. [3].
 50th Ann Announcement Med Dept UL; Session of 1886-87, J. P. Morton, Louisville, KY, 1886, p. [3].
 Ann Announcement Med Dept UL. Session 1906-07, J.P. Morton, Louisville, KY, 1906, p. [2].
10. Brief list of publications:
 1. Roberts WO. Report on Surgery; read before the Ky State Med Soc, April 5, 1882. *Am Pract.* 1882;*25*:321–337.
 2. _____ Aneurism of the Femoral Artery. *Am Pract.* 1883;*28*:193–197.
 3. _____ A Knife Wound of the Intestines. *Am Pract.* 1884;*29*:13–17.
 4. _____ The Progress of Surgery in the 19th Century. *Am Pract & News.* 1901;*31*:241–249.
 5. _____ Hip-joint Amputation: With Report of a Case. *Trans KMA.* 1901;n.s.*9*:54–58.
 6. _____ Southern Surgeons and Surgery — Before, During and After the Civil War. *Trans South Surg & Gyn Assoc.* 1911;*23*:1–24.
11. "Death Comes to Leading Surgeon, Dr. W.O. Roberts," *Louisville times,* April 1, 1921.
12. Obituary, *JAMA.* 1921;*76*:1119.

Introducing the Annual Meeting Speakers



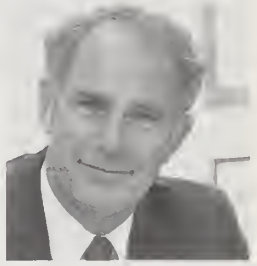
Julian T. Hoff, MD
Ann Arbor, MI
Professor of Surgery and Head, Section of Neurosurgery, The University of Michigan, Ann Arbor. MD, 1962, Cornell University Medical College, New York. President-Elect, American Association of Neurological Surgeons.



Wilma F. Bergfeld, MD
Schaumburg, IL
Cleveland Clinic Foundation, Departments of Dermatology and Pathology; Case Western University, Department of Dermatology, Associate Clinical Professor, Cleveland. MD, 1964, Temple University Medical School, Philadelphia.



John E. Morley, MD
St. Louis, MO
Dammert Professor of Gerontology, St. Louis University Medical Center; Director of the Geriatric Research, Education and Clinical Center, St. Louis Veterans Affairs Medical Center. MD, 1972, University of Witwatersrand, Johannesburg, South Africa.



Leonard J. Kirschner, MD
Phoenix, AZ
Director, Arizona Health Care Cost Containment System, Phoenix. MD, 1961, Albany Medical College, Albany, GA. MPH, 1968, Harvard University, School of Public Health. Fellow, American College of Preventive Medicine.



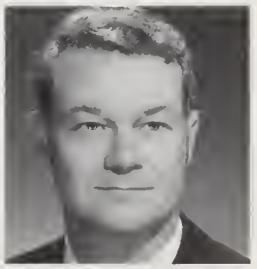
Donald R. Coustan, MD
Providence, RI
Professor and Chairman of Obstetrics and Gynecology, Brown University School of Medicine, Providence, RI. MD, 1968, Yale University School of Medicine.



Carolyn L. Kerrigan, MD
Montreal, Quebec
Surgeon-in-Charge, Division of Plastic Surgery, Royal Victoria Hospital; Professor of Surgery, McGill University, Montreal. MD, 1977, McGill University, Montreal.



Joseph A. Smith, Jr, MD
Nashville, TN
William L. Bray Professor and Chairman, Department of Urology, Vanderbilt University School of Medicine, Nashville. MD, 1974, University of Tennessee, Nashville.



Samuel R. Marney, Jr, MD
Nashville, TN
Associate Professor of Medicine, Chief of Allergy, Vanderbilt University School of Medicine, Nashville. MD, 1960, University of Virginia, Charlottesville.



John S. Sergent, MD
Nashville, TN
Professor of Medicine, Vanderbilt University School of Medicine; Chairman, Department of Medicine, St. Thomas Hospital, Nashville. MD, 1966, Vanderbilt University, Nashville.



Lewis A. Coveler, MD
Houston, TX
Associate Professor of Anesthesiology, Baylor College of Medicine, Houston; and Chief of Anesthesiology, Ben Taub General Hospital. MD, 1970, University of Pittsburgh.



George K. Michalopoulos, MD, PhD
Pittsburgh, PA
Professor of Pathology and Chairman, University of Pittsburgh School of Medicine. MD, 1970, Athens University Medical School, Athens, Greece.



Sandor Feldman, MD
Jackson, MS
Professor of Pediatrics and Chief, Pediatric Infectious Diseases, Children's Hospital, University of Mississippi Medical Center, Jackson. MD, 1967, University of Louisville School of Medicine.

DIAGNOSIS & MANAGEMENT: SPECIAL ISSUES



Randolph Smoak, Jr, MD
Orangeburg, SC
Clinical Professor of Surgery, Medical University of South Carolina; Clinical Associate Professor of Surgery, University of South Carolina School of Medicine. MD, 1959, Medical University of South Carolina. Member, Board of Trustees, American Medical Association.



John B. Bass, Jr, MD
Mobile, AL
Director of Medical Education (for Housestaff Program); Professor of Medicine, Director, Division of Pulmonary and Critical Care Medicine, University of South Alabama College of Medicine, Mobile. MD, 1969, Tulane University, New Orleans.



David E. Schuller, MD
Columbus, OH
Professor and Chairman of the Department of Otolaryngology, and Director of the Comprehensive Cancer Center, Arthur G. James Cancer Hospital and Research Institute, The Ohio State University, Columbus. MD, 1970, Ohio State University College of Medicine.



Thomas H. Mallory, MD
Columbus, OH
Clinical Assistant Professor of Orthopaedic Surgery, Ohio State University, Columbus; Director, Joint Implant Surgeons Fellowship; Chairman of Section, Joint Implant Surgeons Grant Medical Center. MD, 1965, Ohio State University, Columbus.



K. Randall Young, Jr, MD
Birmingham, AL
Director, Division of Pulmonary and Critical Care Medicine, Department of Medicine; and Associate Professor of Medicine, University of Alabama — Birmingham Medical Center. MD, 1978, Jefferson Medical College, Philadelphia.



Keith Wrenn, MD
Nashville, TN
Associate Professor of Emergency Medicine and Associate Professor of Medicine, Vanderbilt University School of Medicine, Nashville. MD, 1976, Emory University School of Medicine, Atlanta.



Michael V. Sivak, Jr, MD
Cleveland, OH
Chief, Division of Gastroenterology, University Hospitals of Cleveland; Professor of Medicine, Case Western Reserve University School of Medicine. MD, 1969, Hahnemann University, Philadelphia. Past President, American Society for Gastrointestinal Endoscopy.



I. Leonard Bernstein, MD
Cincinnati, OH
Clinical Professor of Medicine and Environmental Health; Co-Director of Allergy Research Laboratory and Allergy Training Program, University of Cincinnati Medical Center; Medical Director, Asthma & Allergy Treatment Center, The Deaconess Hospital. MD, 1949, University of Cincinnati Medical School.



Edward J. Holland, MD
Minneapolis, MN
Associate Professor, Director, Cornea and External Disease Service, Department of Ophthalmology, University of Minnesota, Minneapolis. MD, 1981, Loyola-Stritch School of Medicine, Chicago.



Donald E. Fry, MD
Albuquerque, NM
Professor and Chairman, University of New Mexico Department of Surgery, Albuquerque. MD, 1972, Ohio State University, Columbus.

DIAGNOSIS & MANAGEMENT:

SPECIAL ISSUES

Kentucky Medical Association

Scientific Program

W. O. Roberts Meeting

William B. Monnig, MD
KMA President, Presiding

Tuesday, September 28, 1993
Morning General Session
General Sessions Area —
Commonwealth Convention Center

8:30 AM Opening Ceremonies
8:40 AM **"Biomedical Implants: Are the Health Risks Significant?"**
Carolyn L. Kerrigan, MD, Montreal, Canada
9:00 AM **"Difficult Airways: Diagnosis & Management"**
Lewis A. Coveler, MD, Houston, TX
9:20 AM **"Planning for Pregnancy in the Woman with Diabetes: A Golden Opportunity"**
Donald R. Coustan, MD, Providence, RI
9:40 AM **"Hepatitis, AIDS, and the Health Care Worker"**
Donald E. Fry, MD, Albuquerque, NM
10:00 AM **Intermission to Visit Exhibits**
10:30 AM **"Early Detection and Diagnosis of Carcinoma of the Prostate"**
Joseph A. Smith, Jr, MD, Nashville, TN
10:50 AM **"Advances in Management of Closed Head Injury"**
Julian T. Hoff, MD, Ann Arbor, MI
11:10 AM **"Enjoying the Practice of Medicine"**
Thomas H. Mallory, MD, Columbus, OH
11:30 AM **"Management of Ocular Inflammatory Disease"**
Edward J. Holland, MD, Minneapolis, MN

Ky Chapter, American College of Surgeons

General Sessions Area —
Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **"What's New? Microsurgery Update"**
John Derr, MD, Louisville, KY
1:45 PM **"Arterial Crafts for Coronary Bypass Surgery"**
Paul Spence, MD, Louisville, KY
2:00 PM **"Legislative Update"**
The Honorable Bob M. DeWeese, MD, Representative, 48th District, Louisville, KY
2:30 PM **"Repair of Paraneal Aortic Aneurysms"**
Timothy Nypaver, MD, Lexington, KY
2:45 PM **"Mountaineering Medicine"**
Daniel E. Kenady, MD, Lexington, KY
3:00 PM **"Vena Cava Replacement with Peritoneum Lined PTFE Graft"**
Christopher J. Theuer, MD; Thomas M. Bergamini, MD; and R. Neal Garrison, MD, Louisville, KY
3:15 PM **"Enhanced Latissimus Dorsi Muscle Flap Viability for Cardiomyoplasty"**
John Barker, MD, Louisville, KY
3:30 PM **"The Effectiveness of Retionic Acid Inhibition of Squamous Cell Carcinoma Development in a Murine Model"**
Briana Heniford, MD, Louisville, KY
3:45 PM **"Physiology of Multiple Organ System Failure"**
Donald E. Fry, Albuquerque, NM
4:30 PM **"Current Management of Sepsis"**
Steven F. Johnson, MD, Lexington, KY
4:45 PM **"Role of Prognostic Factors in Management of Node-Negative Breast Cancer"**
Patrick C. McGrath, MD, Lexington, KY
5:00 PM Adjournment

KMA Medical Student Section & KMA Resident Physician Section

Meeting Room 105 — Lower Level
Commonwealth Convention Center
Tuesday, September 28, 1993

1:00 PM Welcome — Presidents of the two Sections
1:10 PM Welcome from KMA
1:20 PM News from AMA-RPS/AMA-MSS
1:40 PM **"Changing Dimensions of Medicine"**
. . . Legislative Arena
Don Chasteen, KMA staff
. . . Financing a Medical Career
Scott Black, MD, Barbourville
. . . Choosing Primary Care vs Specialty
H. David Wilson, MD, Lexington
. . . Managed Competition
Robert R. Goodin, MD, Louisville
2:40 PM Question & Answer Session

Ky Neurosurgical Society

Meeting Room 109 — Lower Level —
Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **Scientific Papers**
3:00 PM **Intermission to Visit Exhibits**
3:15 PM **"Changing Attitudes Toward Brain Tumors"**
Julian T. Hoff, MD, Ann Arbor, MI
4:00 PM Business Meeting
4:30 PM **"Special Presentation on Health Care Reform in Kentucky"**
5:00 PM Adjournment

Ky Academy of Eye Physicians and Surgeons

Meeting Room 108 — Lower Level —
Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **"Conjunctival Transplant and Keratoepithelioplasty"**
Edward J. Holland, MD, Minneapolis, MN
2:00 PM **"Diabetes 2000"**
To Be Announced
2:30 PM **Intermission to Visit Exhibits**
2:45 PM **"Peripheral Corneal Thinning Disorders"**
Edward J. Holland, MD, Minneapolis, MN
3:15 PM To Be Announced
4:00 PM Business Meeting
5:00 PM Cocktails/Reception—Gulf Stream/Hialeah Rooms

Ky Society for Plastic & Reconstructive Surgeons

Meeting Room 112 — Lower Level —
Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **"The Effects of Brachytherapy on Wound Healing"**
Scott N. Oishi, MD; Henry C. Vasconez, MD; and Edward A. Luce, MD; Lexington, KY
1:45 PM **"Management of Complications of Osteoradionecrosis"**
Donald R. Conway, MD, Plastic Surgery Resident, University of Louisville
1:57 PM **Resident Presentation — University of Kentucky**
2:09 PM **Resident Presentation — University of Louisville**
2:21 PM **"The Role of the Fresh Cadaver Dissection Lab in Plastic Surgical Training and Research"**
Robert D. Acland, MD, Louisville, KY
2:35 PM **"Palmaris Longus Small Finger Adductorplasty"**
Bruce A. MacDougal, MD, Madisonville, KY
2:57 PM **"Microsurgical Mandibular Reconstruction — Concepts of Evolutionary Progress"**
John W. Derr, MD; Robert D. Acland, MD; Michael B. Flynn, MD; and Joseph C. Banis, Jr, MD; Louisville, KY
3:09 PM **"Microsurgical Perspectives on Distal Vascular Reconstruction of the Lower Extremities"**
Dale Classen, MD; J. David Richardson, MD; and Joseph C. Banis, Jr, MD, Louisville, KY
3:21 PM **"Plantar Glabrous Skin Grafts for Plantar Defects"**
Joseph C. Banis, Jr, MD, Louisville, KY
3:35 PM **"Patterns and Practice of Plastic and Reconstructive Surgery in the Canadian Health Care System"**
Carolyn L. Kerrigan, MD, Montreal, Canada
4:15 PM Business Meeting — Kentucky Society for Plastic and Reconstructive Surgery
5:00 PM Adjournment

Ky Urological Association

Meeting Room 107 — Lower Level —
Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **"Contemporary Issues in Patient Selection for Radical Prostatectomy"**
Joseph A. Smith, Jr, MD, Nashville, TN
2:30 PM **Intermission to Visit Exhibits**
3:00 PM Pyelogram Hour
4:00 PM Annual Business Meeting

Ky OB/GYN Society — Ky Section ACOG

Meeting Room 111 — Lower Level — Commonwealth Convention Center
Tuesday, September 28, 1993

11:45 AM **"Health Care Reform in Kentucky"**
Lunch with Kentucky Legislative Delegation
2:00 PM **"Why, Who and How to Screen for Gestational Diabetes: What to do with the Results"**
Donald R. Coustan, MD, Providence, RI
2:40 PM **"Intrauterine Resuscitation"**
Vernon D. Cook, MD, Louisville, KY
3:15 PM **Intermission to Visit Exhibits**
3:45 PM **"Diagnosis and Management of Endometrial Carcinoma"**
David L. Doering, MD, Louisville, KY
4:15 PM **"Management of Pre-Invasive Vulvar Disease"**
James R. Bosscher, MD, Louisville, KY
4:45 PM Questions and Answers
5:00 PM Adjournment

Ky Society of Anesthesiologists

Meeting Room 106 — Lower Level — Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **"The Management of Difficult Airways & Failed Intubations"**
Lewis A. Coveler, MD, Houston, TX
2:15 PM **"The Rational Choice & Indications for Inotropes in the Perioperative Period"**
William Soden, MD, Park Ridge, IL
3:00 PM **Intermission to Visit Exhibits**
3:30 PM **"Practical Aspects of Pediatric Anesthesia"**
John T. Algren, MD, Houston, TX
4:15 PM **"The Role of Neuroblockade in the Management of Headache Pain"**
Michael C. Cronen, DO, Louisville, KY
5:00 PM **"Risk Management and Health Care Reforms for the 90's"**
Larry P. Griffin, MD, Louisville, KY
5:45 PM Adjournment

The Kentucky Medical Association is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

Ky Orthopaedic Society

Meeting Room 104 — Lower Level — Commonwealth Convention Center
Tuesday, September 28, 1993

1:30 PM **Welcoming Remarks**
K. Thomas Reichard, MD, President, Louisville, KY
Jeffrey W. Parr, MD, Program Chair, Lexington, KY
1:35 PM **"Poly Wear in Total Joint Arthroplasty"**
Donald L. Pomeroy, MD, Louisville, KY
1:50 PM **"Coral Bone Substitute for Metaphyseal Defects"**
David E. Bordon, MD; David Seligson, MD; Susumu Sugita, MD; Louisville, KY
2:05 PM **"The Conjoint Nerve Root"**
H. Brooks Morgan, MD, Lexington, KY
2:20 PM **"Comparison of a Calcar Deficient Cementless Long Stem to a Cementless Long Stem in Total Hip Revision Arthroplasty"**
Lawrence A. Schaper, MD, Louisville, KY
2:35 PM **Intermission to Visit Exhibits**
3:05 PM **"Bone Loss in Total Hip Replacement — Stress Shielding Versus Osteolysis"**
Thomas H. Mallory, MD, Columbus, OH
4:00 PM **"Spinal Balance After Cotrel-Dubousset Fixation in Idiopathic Scoliosis"**
David B. Stevens, MD, Lexington, KY
4:15 PM **"Clinical Results of Rotator Cuff Repair"**
Richard A. Sweet, MD, Louisville, KY
4:30 PM **"Degenerative Lumbar Scoliosis Treated by Anterior/Posterior Fusion"**
John J. Vaughan, MD, Lexington, KY
Richard T. Holt, MD, Louisville, KY
4:45 PM **"Socioeconomic"**
To Be Announced
5:15 PM **"A Joint Parade"** 6-12-94
John R. Allen, MD, Lexington, KY
5:30 PM Business Meeting
K. Thomas Reichard, MD, Louisville, President
6:00 PM Reception & Dinner
Vincenzo's Restaurant

- Residents, Office Personnel and Hospital Staff are welcome to attend Scientific Program



Sonia R. Teller, MD, Chairperson Scientific Program Committee, Presiding

Wednesday, September 29, 1993
Morning General Session
General Sessions Area —
Commonwealth Convention Center

8:30 AM Announcements
8:40 AM **"Ambulatory Antibiotic Selection in the Pediatric Population"**
Sandor Feldman, MD, Jackson, MS
9:00 AM **"An Overview of Family Violence"**
Randolph D. Smoak, Jr, MD, Chicago, IL
9:20 AM **"Asthma Morbidity and Mortality: Working Toward Resolution"**
K. Randall Young, Jr, MD, Birmingham, AL
9:40 AM **"Health Care Reform: One Physician's Perspective on the Year 2000"**
John S. Sergent, MD, Nashville, TN
10:00 AM **Intermission to Visit Exhibits**
10:30 AM **"Virtual Reality — Possible New Aid to Diagnosis and Management"**
David E. Schuller, MD, Columbus, OH
10:50 AM **"Drug Resistant Tuberculosis"**
John B. Bass, Jr, MD, Mobile, AL
11:10 AM **"Molecular Diagnostics"**
George K. Michalopoulos, MD, PhD
Pittsburgh, PA
11:30 AM **"Allergy Immunotherapy: From Anti-Toxin to Peanuts"**
Samuel R. Marney, Jr, MD, Nashville, TN
11:50 AM **PRESIDENT'S LUNCHEON**

President's Installation & Awards Luncheon

Wednesday, September 29 — 11:50 AM
Regency Ballroom — Hyatt Regency Hotel

William B. Monnig, MD
KMA President, presiding

Invocation
Recognition

Awards Presentation
Nelson B. Rue, Bowling Green
Chairman, KMA Awards Committee

Installation of new KMA President

Ky Pediatric Society

Meeting Room 105 — Lower Level —
Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"The Role of Acyclovir in the Treatment of Varicella Zoster Virus Infections in Children"**
Sandor Feldman, MD, Jackson, MS
3:00 PM **Intermission to Visit Exhibits**
3:30 PM **"Our Most Important Resource — Are We Doing Our Part to Keep Them Alive? (Injury Prevention in Your Practice)"**
Susan Pollack, MD, Lexington, KY
4:00 PM **"Norplant — An Overview"**
Paige Hertweck, MD, Louisville, KY
4:30 PM Business Meeting
5:00 PM Adjournment

Ky Psychiatric Association

Meeting Room 110 — Lower Level —
Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"Violence Against Women — The Price for Intimacy"**
Randolph D. Smoak, Jr, MD, Chicago, IL
3:15 PM Questions and Answers
3:25 PM **Intermission to Visit Exhibits**
4:00 PM **"The Video Violence Debate"**
LTC Raymond G. Lande, MD, Washington, DC
5:00 PM KPA General Meeting
5:30 PM Adjournment

Ky Chapter, American Academy of Family Physicians

Meeting Room 106 — Lower Level —
Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"From Controversial Issues to Prudent Asthma Therapy"**
K. Randall Young, Jr, MD, Birmingham, AL
3:00 PM **Intermission to Visit Exhibits**
3:30 PM **"Upcoming Changes in Medical Review in Kentucky"**
William G. Davis, MD, Louisville, KY
3:40 PM **"Presentation on Current Status of Family Physicians as It Relates to Health Care Reform in Kentucky"**
Ronald E. Waldridge, MD, Shelbyville, KY
4:15 PM Adjournment

Ky Chapter American College of Physicians

Meeting Room 108 — Lower Level — Commonwealth Convention Center
Wednesday, September 29, 1993

2:00 PM **"Associate Presentations from UL and UK"**
2:45 PM **"Controversies in Rheumatology"**
(Four major areas of concerns to primary care physicians)
John S. Sergent, MD, Nashville, TN
3:30 PM **Intermission to Visit Exhibits**
3:45 PM **"Sleep Apnea"**
Eugene Fletcher, MD, Louisville, KY
4:15 PM **Department of Medicine — Department Update — University of Louisville, University of Kentucky**
4:45 PM Adjournment

Ky Society of Otolaryngology Head & Neck Surgery, Inc.

Meeting Room 111 — Lower Level — Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"Vestibular Neurectomy — The University of Kentucky Experience"**
Raleigh O. Jones, Jr, MD, Lexington, KY
2:30 PM **"Evaluation and Management of the Neonatal Airway"**
Toni M. Ganzel, MD, Louisville, KY
3:00 PM **"Role of Microvascular Surgery in Head and Neck Reconstruction — 1993"**
Joseph Valentino, MD, Lexington KY
3:30 PM **Intermission to Visit Exhibits**
4:00 PM **"Reconstruction of the Cranial Base"**
David E. Schuller, MD, Columbus, OH
5:00 PM **"Craniofacial Surgery for the Otolaryngologist"**
Khalid Chowdhury, MD, Lexington, KY
5:20 PM **"Robotics in Otolaryngology"**
Kevin T. Kavanagh, MD, Somerset, KY
5:45 PM Adjournment

Ky Chapter, American College of Chest Physicians

Meeting Room 104 — Lower Level — Commonwealth Convention Center
Wednesday, September 29, 1993

1:30 PM **"Cardiopulmonary Complications of Sarcoidosis"**
Joseph P. Lynch, lll, MD, Ann Arbor, Ml
2:15 PM **"Stunned and Hibernating Myocardium"**
Kanu Chatterjee, MD, San Francisco, CA
3:00 PM **Intermission to Visit Exhibits**
3:30 PM To Be Announced
4:15 PM **"Tuberculosis in the 1990s"**
John B. Bass, Jr, MD, Mobile, AL
5:00 PM Adjournment

Ky Society of Pathologists

Meeting Room 109 — Lower Level — Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"Liver Regeneration: Biological and Clinical Aspects"**
George K. Michalopoulos, MD, PhD
Pittsburgh, PA
3:00 PM **Intermission to Visit Exhibits**
3:30 PM **"Liver Regeneration: Biological and Clinical Aspects"**
George K. Michalopoulos, MD, PhD
Pittsburgh, PA
4:15 PM Business Meeting
5:15 PM Adjournment

Ky Society of Allergy & Clinical Immunology

Meeting Room 107 — Lower Level — Commonwealth Convention Center
Wednesday, September 29, 1993

2:15 PM **"Diagnosis and Therapy of Sinusitis"**
Samuel R. Marney, Jr, MD, Nashville, TN
3:00 PM **Intermission to Visit Exhibits**
3:30 PM **"Liability Aspects of Health Care Delivery Reform"**
Larry P. Griffin, MD, Louisville, KY
4:00 PM Adjournment

DIAGNOSIS & MANAGEMENT: SPECIAL ISSUES

Ky Chapter American College of Cardiology

Hialeah Room
Hyatt Regency Hotel
Wednesday, September 29, 1993

4:00 PM Business Meeting — Chapter Officers and Councilors
5:00 PM Reception and Dinner — Vincenzo's Restaurant

Ky Chapter, American College of Emergency Physicians

Meeting Room 109 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM **"Ethical Issues in Emergency Medicine"**
Keith Wrenn, MD, Nashville, TN
10:00 AM **Intermission to Visit Exhibits**
10:30 AM Ky Chapter, American College of Emergency Physicians Chapter Meeting
11:30 AM Adjournment

Ky Occupational Medical Association

Meeting Room 106 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM **"Occupational Lung Diseases"**
I. Leonard Bernstein, MD, Cincinnati, OH
10:00 AM **Intermission to Visit Exhibits**
10:30 AM **"Diagnosis and Management of Work Related Dermatitis"**
Joseph F. Fowler, MD, Louisville, KY
11:00 AM **"Carpal Tunnel Syndrome Update"**
B. Thomas Harter, Jr, MD, Louisville, KY

Ky Association of Public Health Physicians

Meeting Room 104 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM **"Health Care Financing"**
Leonard J. Kirschner, MD, Phoenix, AZ
9:45 AM **Intermission to Visit Exhibits**
10:15 AM **"Prevention in Health Care Reform"**
Rice C. Leach, MD, Frankfort, KY
11:00 AM Business Meeting
12 NOON Adjournment

Ky Geriatrics Society

Meeting Room 110 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM **"Hypercholesterolemia in the Elderly: To Treat or Not to Treat?"**
John E. Morley, MD, St. Louis, MO
9:50 AM **"The Role of Zinc in Healthy Aging"**
Craig J. McClain, MD, Lexington, KY
10:40 AM **Intermission to Visit Exhibits**
11:10 AM **"Nutritional Assessment of the Elderly. Why? When? What's New?"**
Christine L. Tulley, MD, Lexington, KY
12 NOON **Intermission to Visit Exhibits and Move to Hyatt Regency**
12:30 PM Business Meeting/Luncheon — Kentucky Suite

Ky Academy of Physical Medicine and Rehabilitation

Meeting Room 103 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM Business Meeting
9:30 AM **Resident Research Presentations**
University of Kentucky
University of Louisville
10:30 AM **Intermission to Visit Exhibits**
11:00 AM **"Problems in the Diagnosis and Management of the Worker's Compensation Case"**
Robert P. Christopher, MD, Memphis, TN
12 NOON Adjournment

Ky Society for Gastrointestinal Endoscopy

Meeting Room 105 — Lower Level —
Commonwealth Convention Center
Thursday, September 30, 1993

9:00 AM **"Endoscopic Ultrasound"**
Michael Sivak, MD, Cleveland, OH
9:45 AM **"The Role of ERCP in the Management of Laparoscopic Bile Duct Injuries"**
Grady J. Stephens, MD, Louisville, KY
9:57 AM **"Standardization of Clinical Criteria Required or Use of 12.5 mm Barium Tablet"**
Stephen A. McClave, MD, Louisville, KY
10:09 AM **"One Stage Gastrostomy Button"**
Todd Marion, MD, Lexington, KY
10:21 AM **Intermission to Visit Exhibits**
10:51 AM **"GI Complications of Eating Disorders"**
Nick Nickl, MD, Lexington, KY
11:03 AM **"The Role of Laparoscopic Cholecystectomy in the Management of Acute Biliary Pancreatitis"**
Tony Delorio, MD, Louisville, KY
11:15 AM **"Do the Ductular Alterations of Chronic Pancreatitis Also Occur in the Parotid Gland in Response to Chronic Ethanol Ingestion?"**
To Be Announced
11:27 AM **"Wire-Guided Endoscopically — Placed Feeding Tubes"**
Boulos Toursarkissian, MD, Lexington, KY
11:39 AM **"Early Enteral Feeding in Pancreatitis"**
William Simpson, MD, Lexington, KY
12 NOON **Board Meeting**
12:30 PM **Reception/Luncheon**

Ky Dermatological Society

Louisville, KY
Thursday, September 30, 1993

1:00 PM **Case Presentations**
310 E. Broadway, Louisville, KY
2:00 PM **Break**
Norton Hospital Auditorium
2:30 PM **"Cosmetics — Are They Safe?"**
Wilma F. Bergfeld, MD, Cleveland, OH
3:00 PM Case Discussion
4:30 PM Business Meeting
5:00 PM Adjournment

CONTINUING MEDICAL EDUCATION

The Kentucky Medical Association designates this continuing medical education activity for 15.0 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association. One credit hour may be claimed for each hour of participation by the individual physician.

"Be our Guest"

If you are a physician age 40 years or younger, or

if you've been in practice 5 years or less...

Be our guest and join your colleagues at a

luncheon being held during KMA's Annual Meeting

Tuesday, September 28, 1993

12:00 noon

Keeneland Suite - Hyatt Regency Louisville

Speaker - Joy Maxey, MD,

Immediate Past Chair, AMA-YPS

To reserve a lunch, please call (502) 426-6200

(Spouses welcome)

Make plans to attend!

DIAGNOSIS & MANAGEMENT: SPECIAL ISSUES

General Sessions Learning Objectives

Advances in Management of Closed Head Injury
Julian T. Hoff, MD
To update practitioners on current methods to treat closed head injury. To establish an appreciation of the problems faced by those with mild head injury. To inform practitioners of new drug trials in severe closed head injury patients. To discuss optimal diagnostic tests available today.

Early Detection and Diagnosis of Carcinoma of the Prostate
Joseph A. Smith, Jr, MD
To review the issues involved in early detection and screening for carcinoma of the prostate. The natural history of early prostate cancer will be discussed and pertinent aspects of the epidemiology will be introduced. The role of prostate specific antigen, digital rectal examination, and transrectal ultrasound will be reviewed. Recommendations regarding who, when, and how to screen for carcinoma of the prostate will be made.

Management of Ocular Inflammatory Disease
Edward J. Holland, MD
Following this lecture, the participants should be able to: (1) Recognize inflammatory diseases of the eye; (2) associate inflammatory diseases of the eye with systemic disorders; and (3) better assist in the systemic treatment of ocular inflammatory disorders.

Enjoying the Practice of Medicine
Thomas H. Mallory, MD
Objective is to pursue the professional satisfaction in the practice of medicine. Topics to be discussed are: The historical role of the physician in contemporary society; finding and clarifying political and social forces; analyzing physician lifestyles; discussing areas of vulnerability; and make suggestions as to what can be considered prudent to creating an enjoyable practice of medicine. The discussions will broaden understanding, clarify priorities, and lead to practice enrichment and perception.

Allergy Immunotherapy: From Anti-Toxin to Peanuts
Samuel R. Marney, Jr, MD
Understanding of the indications, mechanisms, and limitations of allergy immunotherapy.

Ambulatory Antibiotic Selection in the Pediatric Population
Sandor Feldman, MD
Selection of Oral Antibiotics: (1) In vitro sensitivities; (2) clinical studies; (3) adverse effects; (4) cost; and (5) compliance. The purpose of this presentation is to orient the physician to use the above five criteria in the selection of oral antibiotics.

Drug Resistant Tuberculosis
John B. Bass, Jr, MD
Understand the current epidemiology of drug resistant tuberculosis in the United States. Identify risk factors for transmission of drug resistant tuberculosis. Identify appropriate initial therapy for patients with possible drug resistant tuberculosis. Outline the major problems associated with TB therapy utilizing second line drugs.

Planning for Pregnancy in the Woman with Diabetes: A Golden Opportunity
Donald R. Coustan, MD
At the conclusion of this presentation, the participant will be able to: (1) Understand the importance of good glucose control prior to diabetic pregnancy in preventing birth defects; and (2) be able to effectively counsel women with diabetes regarding preparation for pregnancy.

An Overview of Family Violence
Randolph D. Smoak, Jr, MD
This presentation will give an overview of family violence which has surfaced as a significant medical concern. Little attention has been paid to this topic over the years which has reached epidemic proportions with an estimated 8 to 12 million women in the United States at risk of being abused by their current or former intimate partners. Violence causes serious physical, psychological, and social sequelae of these women and their families. Some facts pertaining to this subject will probably be surprising to the participants. The various forms of abuse will be outlined and some pointers given for the interviewing process. This is an art in the practice of medicine after one has initially developed some suspicion of this diagnosis. The diagnostic and clinical findings will be reviewed. A discussion regarding the intervention process will outline the responsibilities of all parties and the methods of utilizing the various local resources.

The following will be focused upon in a pertinent way: (1) How physicians can identify abuse in their patient encounters. (2) Developing a comfortable atmosphere to encourage patients to discuss abuse. (3) The importance of knowing and making use of local referral services — psychiatric care, social services, temporary shelters, etc.

Biomedical Implants: Are the Health Risks Significant?
Carolyn L. Kerrigan, MD
To bring the practitioner up-to-date on: (a) Current issues surrounding biomedical implants with specific reference to breast implants; (b) diagnostic tests useful in investigating patients with complications from biomedical implants; and (c) treatment options in patients with complications from biomedical implants.

Molecular Diagnostics
George K. Michalopoulos, MD
Molecular Diagnostics is the extrapolation of molecular biology into the diagnostic laboratory. The discoveries on the role of genes and products and regulation of cell growth and differentiation have now become valuable diagnostic tools for diagnosis and treatment of tumors, infectious diseases, inflammatory diseases, etc. The practice of medicine and the diagnosis at the laboratory level is bound to be revolutionized in the next two decades in the application of molecular diagnostics. Clinical practitioners, as well as people in laboratory medicine, need to build teams where the principles of molecular diagnostics are mastered. Their usefulness is fully taken advantage of. It will be a challenge to determine the magnitude of application of molecular diagnostics in the upcoming world of tight reimbursement for medical expenses.

Difficult Airways: Diagnosis & Management
Lewis A. Coveler, MD
At the completion of this lecture the attendee will be able to: (1) Describe basic airway evaluation techniques used to determine the degree of difficulty that should be anticipated during endotracheal intubation;

(2) describe the various routes of intubation and the indications and contraindications for each; (3) describe basic management techniques for the problem airway; and (4) define those circumstances in which expert consultation in airway management is desirable.

Virtual Reality — Possible New Aid to Diagnosis and Management
David E. Schuller, MD
To expand the level of understanding and virtual reality and its implications in diagnosis and therapy in medicine.

Asthma Morbidity and Mortality: Working Toward Resolution
K. Randall Young, Jr, MD
At the conclusion of the program, the audience should: (1) Understand current thinking about causes for upward trends in asthma morbidity and mortality; and (2) understand the emphasis currently being placed on anti-inflammatory therapy for asthma.

Health Care Reform: One Physician's Perspective on the Year 2000
John S. Sergent, MD
Why reform is inevitable, regardless of Hillary: (a) Why the country that has the best hospitals, the best doctors, the best research, and spends the most money on health care does not have the best health care system in the world. What will happen to hospitals: (a) Will the hospital of the future be an intensive care unit surrounded by ambulatory facilities? How about doctors: (a) the role of specialists; and (b) the role of the generalist.

AN INVITATION TO ALL SENIOR AND/OR RETIRED MEMBERS OF KMA TO THE STATEWIDE CATO SOCIETY MEETING OF THE SENIOR PHYSICIANS OF JEFFERSON COUNTY 9:30 AM WEDNESDAY, SEPTEMBER 29, 1993 THE HYATT REGENCY HOTEL, LOUISVILLE, KY

Here is an opportunity for senior and/or retired members of KMA to meet old colleagues and make new friends at the 4th Annual Statewide CATO Society Meeting, held during the KMA Annual Meeting.

The CATO Society is an integral part of the Jefferson County Medical Society and its Senior Physicians Committee. We have meetings in the Spring and Fall that are primarily for fellowship. We gather for a light meal followed by an enlightening but brief address on some informative or entertaining topic.

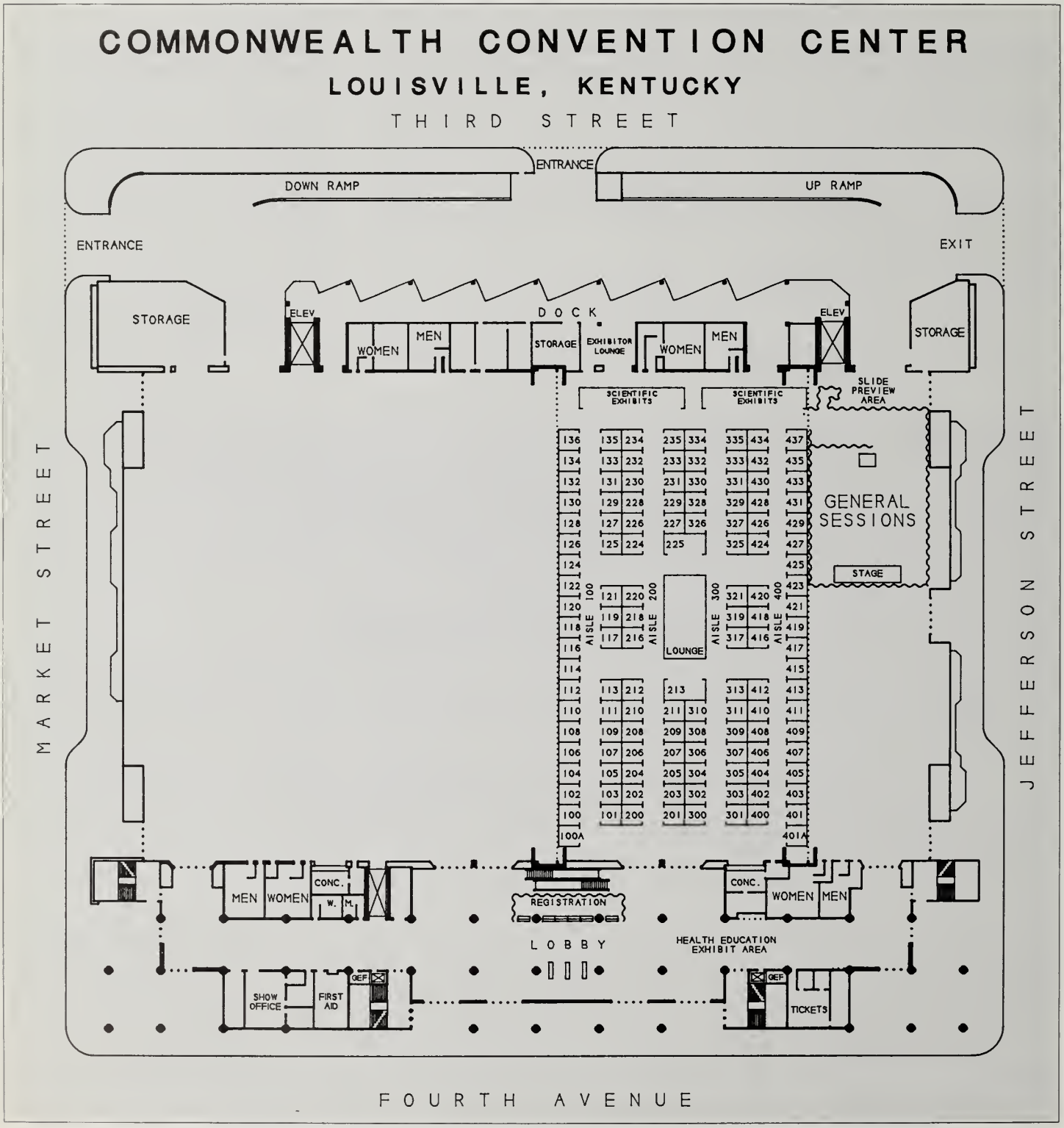
Last year's meeting was an immense success with a large crowd of senior physicians from the Kentuckiana area.

Watch the mail for your invitation, complete the form, and share a time during brunch with your colleagues. We look forward to visiting with you.

G. William Pedigo, MD
Chairman, Statewide CATO Society

Eugene H. Conner, MD
President, Jefferson County CATO Society

EXHIBIT HALL FLOOR PLAN



All exhibitors with corresponding booth space(s) are listed on this map of the Exhibit Hall. We regret that due to printing and publication deadlines, not all exhibitors are represented in this Exhibit Guide. For more detailed information on the exhibitors, refer to the Technical Exhibits listing beginning on page 368, and please visit them in the Exhibit Hall.

TECHNICAL EXHIBITOR DIRECTORY

Exhibitor	Booth
Abbott Laboratories	213
Advanced Computer Technologies, Inc.	307
Advanced Tel-Imaging, Ltd	418
Alliant Health System	203
Astra/Merck	204
Basel Pharmaceuticals	311
Berlex Laboratories	201
Blue Cross & Blue Shield of Kentucky	218
Burroughs Wellcome Company	224
CaduSys Medical Systems	304
Cardinal Hill Hospital	432
Carnrick Labs	306
Caretenders Healthcorp	303
Central Pharmaceuticals, Inc	231
Charter Hospitals of Kentucky	404
Ciba Pharmaceuticals	429
Clayton L. Scroggins Associates, Inc	425
Clintec Nutrition Company	232
Coastal Emergency Services of Memphis, Inc	405
Daniels Pharmaceuticals, Inc	210
Division of Disability Determinations	332
Dodson Group	417
Eli Lilly & Company	317
Fisons Pharmaceuticals	437
Floyd Memorial Hospital	413
Fujisawa USA, Inc	135
Glaxo Pharmaceuticals	328 & 330
Good Samaritan Hospital	420
Gregory and Associates, Inc	333
Grogan's Healthcare Supply	227
Healthware, Inc	327
HOECHST-Roussel Pharmaceuticals, Inc	325
Holdaway Medical Services	409
Homedco	230
Image Technology, Inc	228
Ispec, Inc.	118
J.B. Lippincott Company	300
Jefferson Hospital	205
Jewish Hospital HealthCare Services	401A
Kentucky Air National Guard	329
Kentucky Army National Guard	319
Kentucky Medical Insurance Company/ United Leasing, Inc	114 & 116
Kentucky Medical Review Organization	102
Kentucky Organ Donor Affiliates	428
Kentucky Telco Federal Credit Union	100A
Key Pharmaceuticals	435
Knoll Pharmaceutical Company	412
Lakeview Rehab Hospital	133
Lederle Laboratories	301
Lincoln Trail Hospital	234
Marion Merrell Dow, Inc	233 & 235
Mark Kidd Studios of Kentucky	308
Maxim Medical	119
Mead Johnson Nutritionals	313
Mead Johnson Pharmaceuticals	216
Medic Computer Systems	103
Medical Management Consultants, Inc	406
Medical Management Resources, Inc.	211
The Medical Protective Company	225
Merck Human Health Division	407
Metropolitan Reference Laboratories, Inc	433
Miles Pharmaceuticals	434
Mosby/Churchill/Waverly	402
National Health Laboratories	126
Olsten HealthCare	427
Ortho Pharmaceutical Corporation	101
Our Lady of Peace Hospital	424
Parke-Davis	121
P.C. Products	209
Pfizer Labs	305
Physicians Financial Services, Inc	112
The PIE Mutual Insurance Co	416
Pratt Pharmaceuticals/Pfizer, Inc	310
Princeton Pharmaceutical Products	125
RANAC Computer Corporation	335
RCFA Physician Managers	309
Ransdell Surgical, Inc	212
Reed and Carnrick Pharmaceuticals	127
Republic Bank & Trust Company	229
Rhone-Poulenc Rorer Pharmaceuticals	408
Roche Biomedical Laboratories, Inc	415
Roche Laboratories	410
Roerig Division of Pfizer, Inc	334
Ross Laboratories	200
Saint Joseph Hospital	134 & 136
Salcris Systems	423
Sandoz Pharmaceuticals	120
Sanofi-Winthrop Pharmaceuticals	426
Savage Laboratories	113
Schering Laboratories	207
SKYCARE	401
Smith Barney Shearson	326
SmithKline Beecham Clinical Labs	220
SmithKline Beecham Pharmaceuticals	302
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TECHNICAL EXHIBITS

Plan to visit the Exhibit Hall during the KMA Annual Meeting. Trained professional representatives of more than 120 firms will be on hand to discuss with you the details of their products and services in a relaxed atmosphere — with no patients waiting in your outer office and with no telephones ringing.

Located in the Commonwealth Convention Center, the exhibits will condense a volume of information and ideas in such a manner that a vast amount of knowledge can be secured in a short period of time.

The Exhibit Hall is an important part of the Annual Meeting and is the site of registration for all CME courses.

Thirty-minute intermissions have been planned during each general and specialty group session so that every physician may take advantage of this opportunity to benefit their practice and their patients.

Abbott Laboratories **#213**
One Abbott Park Road
Abbott Park, IL 60064-3500
(708) 937-7141
You are cordially invited to visit the Abbott booth which will feature Biaxin™ (clarithromycin) and Hytrin® (terazosin HCl). Please check at the exhibit to see what's new!

Advanced Computer Technologies, Inc **#307**
225 E Normandy Court
Nicholasville, KY 40356
(606) 885-1289
ACT Inc has been in business since 1987. Specializing in servicing small to medium businesses, ACT offers hardware, software, consulting, networking, multimedia, custom programming, and service on all IBM PCs and compatibles. We are proud to be Kentucky's only authorized COMPUMEDIC dealer. COMPUMEDIC, a complete medical practice management system, has inventory management, general ledger, accounts payable, resource scheduler, full audit trail, multiple fee schedules, missed treatments, statistics, patient recall, user designed reports, electronic claims, HMO/PPO evaluation, and more. COMPUMEDIC is recognized in the Medicare Electronic Billing Hall of Fame. Please meet us at booth #307 for a thorough demonstration.

Advanced Tel-Imaging, Ltd **#418**
4201 Connecticut Ave, NW #310
Washington, DC 20008
(202) 244-3359
ATI identifies the need for diagnostic radiology services. We offer a turnkey solution, including X-ray capabilities and teleradiology services that offer the primary care physician instant consultation with a specialist.

Alliant Health System **#203**
PO Box 35070
Louisville, KY 40232-5070
(502) 629-8659

Astra/Merck **#204**
301 S Perimeter Park, Suite 100
Nashville, TN 37211
(615) 781-4277

Basel Pharmaceuticals **#311**
3022 Peale Ave
Louisville, KY 40205
(502) 451-8805

Berlex Laboratories **#201**
300 Fairfield Road
Wayne, NJ 07470
(201) 305-5082

Blue Cross and Blue Shield of KY **#218**
9901 Linn Station Road
Louisville, KY 40223
(502) 423-2150
Provider Services representatives will be available during the exhibit with information about Blue Cross and Blue Shield of Kentucky programs.

Burroughs Wellcome Company **#224**
3030 Cornwallis Road
Research Triangle Park, NC 27709-2700
(919) 248-3000

CaduSys Medical Systems **#304**
4012 Dupont Circle, Suite 203
Louisville, KY 40207
(502) 896-1768
Cadu . . . the Office Assistant from CaduSys Medical Systems, is an office automation system for the health care professional consisting of computers, printers, and software. This system meets the needs of a physician's fast paced office recording procedures, such as patient billing, paper and electronic insurance claims processing, appointment tracking, recall reporting, clinical information processing and management reporting including: aged receivables, day sheet, insurance charge and payment information, and doctor and/or office performance reports.

Cardinal Hill Rehabilitation Hospital **#432**
2050 Versailles Road
Lexington, KY 40504
(606) 254-5701
Cardinal Hill Rehabilitation Hospital is a nonprofit physical rehabilitation center which provides a wide range of therapy and services for adults and children with all types of disabling conditions. A full range of physical rehabilitation specialists work as a team to meet the individual needs of each patient. Cardinal Hill is accredited by CARF and JCAHO. We welcome the opportunity to discuss our programs. Staff will be present to answer questions.

Caretenders Healthcorp **#303**
9200 Shelbyville Road, Suite 810
Louisville, KY 40222
(502) 425-4707

Carnrick Labs, Inc **#306**
65 Horse Hill Road
Cedar Knolls, NJ 07927
(201) 267-2670
Providing cost-effective brand name pharmaceuticals since 1899.

Central Pharmaceuticals, Inc **#231**
PO Box 328
Seymour, IN 47274
(812) 522-3915

Charter Hospitals of Ky **#404**
3050 Rio Dosa Dr
Lexington, KY 40509
(606) 269-2325
Charter Medical Corporation operates three facilities in Kentucky which offer inpatient psychiatric and addictive disease programs for children, adolescents and adults. Our facilities in Lexington and Louisville also offer outpatient services, with the facility in Paducah offering a residential treatment program for adolescents. Each facility offers free screenings with our Needs Assessment and Referral Centers open seven days a week, 24 hours a day.

Ciba Pharmaceuticals **#429**
292 Beckman Ave
St. Henry, OH 45883
(419) 678-8528

Clayton L. Scroggins Associates, Inc **#425**
200 Northland Blvd
Cincinnati, OH 45246
(502) 636-0825
Management consultants to the medical arts. Scroggins Associates has served medical practices for nearly 50 years, assisting physicians in every specialty — both solo and group practices — run their businesses successfully and profitably, freeing you and your staff to do what you do best — deliver quality care.

Clintec Nutrition Company **#232**
Three Parkway, Suite 500
Deerfield, IL 60015-0760
(708) 317-2800
Clintec Nutrition Company, affiliated with Baxter Healthcare and Nestle SA, offers a full line of enteral and parenteral nutrition products. Nutritional management of patients from TPN to oral supplementation is now possible through one company. The Ultrapak closed feeding system offers state-of-the-art delivery in a non-air-dependent bag.

Coastal Emergency Services of Memphis, Inc **#405**
5885 Ridgeway Center Pkwy #113
Memphis, TN 38120
(901) 767-1301
We provide practice management services for Emergency Departments. Physicians contract with our company to provide staffing in Emergency Departments.

Daniels Pharmaceuticals, Inc **#210**
2517 25th Ave N
St Petersburg, FL 33713
1-800-237-7427
Levoxine® (Levothyroxine Sodium Tablets, USP) is a brand name product available in eleven strengths for consistent quality thyroid replacement therapy. Daniels' rigorous quality control policies assures batch to batch uniformity as evidenced by our unblemished record of no recalls. We excel at delivering quality products at cost effective prices.

Division of Disability Determinations **#332**
PO Box 1000
Frankfort, KY 40601
(502) 564-8050
Obtaining good medical evidence and maintaining an adequate panel of consulting physicians is vital to the functioning of the Social Security Disability Program. Representatives of the Kentucky Division of Disability Determinations Services (DDS) exhibit at professional medical conventions at local and state levels to promote understanding of the medical needs of the disability program. Through understanding, the medical community and DDS can work together to serve the needs of Kentucky's disabled.

Dodson Group **#417**
9201 State Line
Kansas City, MO 64114
1-800-825-3760
Dividend program for Workers' Compensation Insurance approved by Kentucky Medical Association.

Eli Lilly and Company **#317**
Lilly Corporate Center
Indianapolis, IN 46285
(317) 276-2554
Eli Lilly and Company welcomes the opportunity to support your organization through participation in your exhibit program. We cordially invite you to visit our display and discuss any inquiries you may have concerning Lorabid™ (loracarbef, Lilly) and Humulin® (human insulin of recombinant DNA origin, Lilly).

Fisons Pharmaceuticals **#437**
9013 Bingham Dr
Louisville, KY 40242
(502) 425-6352
Fisons has long been recognized as a worldwide leader in asthma and allergy research. In keeping with that tradition Fisons is pleased to introduce an exciting new drug for asthma. Tilade treats not just the symptoms of asthma, but is a true disease-modifying agent. Please stop by our booth for more information on how this drug can benefit your patients.

Floyd Memorial Hospital **#413**
1850 State St
New Albany, IN 47150
1-800-582-4547 or 1-800-423-1513 (Indiana)
Floyd Memorial Hospital (FMH) is the largest acute care facility in southern Indiana. With a service area of 250,000, FMH provides the most advanced technology available today, along with immediate expert consultations in more than 29 specialties. Our Level II Trauma Center is staffed by board certified emergency physicians with 24-hour coverage. Floyd County is a diverse community offering charm and security for its 65,000 citizens while bordering the major metropolitan area surrounding Louisville. Stop by our booth and discuss practice opportunities in Floyd County, Indiana.

Fujisawa USA, Inc **#135**
Three Parkway N
Deerfield, IL 60015
(708) 317-8623
Fujisawa USA, Inc will have representatives available to discuss CEFIZOX® (Ceftizoxime), a third generation cephalosporin; NEBUPENT™ (Pentamidine Isethionate) for inhalation solution — for use in prophylaxis in HIV infected individuals considered at high risk for Pneumocystis carinii pneumonia; and ADENOCARD® (Adenosine), an injectable antiarrhythmic used for the treatment of paroxysmal superventricular tachycardia.

Glaxo, Inc **#328 & 330**
5 Moore Drive
Research Triangle Park, NC 27709
(919) 248-2100

Good Samaritan Hospital **#420**
310 South Limestone St
Lexington, KY 40508-3008
(606) 252-6612
Good Samaritan's exhibit will feature state-of-the-art laser technologies; the opening of a dedicated Pain Care Center; the enhancement of mental health programs, and information about other new and exciting services, building on the foundation of the hospital's traditional leadership in quality orthopedics and neurosciences programs. In addition, both audio-visual and print materials will provide information about the full range of other high quality, acute care services available at the hospital.

Gregory and Associates, Inc, Nutrition Management **#333**
9707 Shelbyville Road
Louisville, KY 40223
(502) 426-8224
Providing private consult opportunities for area physicians for over twenty years, Gregory and Associates are specialists in nutrition management for home health services, long term care, and acute care facilities. Whether in Kentucky, Indiana, or Ohio, family practitioners and physician specialists can now easily provide cost effective nutrition intervention that will enhance any pa-

tient's treatment plan. Our staff of highly qualified Registered Dietitians, Certified Nurse Support Dietitians, and Certified Diabetic Educators will bring a personal caring approach to your patients as they design effective lifestyle and nutritional treatment plans. Reimbursement and scheduling concerns are handled by us, enabling more productive time for your staff. Whether by RD placement within your office, or patient referral to our area locations, let our professional RD staff become your newest allied health team member! See our representative in the Exhibitor's Hall, Booth Number 333!

Grogan's Healthcare Supply **#227**
1016 S Broadway
Lexington, KY 40504
(606) 254-6661
Join us in the Grogan's booth for a close look at the latest Midmark exam room furniture plus other office equipment.

Healthware, Inc **#327**
340 N. Dixie Blvd
Radcliff, KY 40160
(502) 351-2244
Healthware, Inc specializes in automating physicians' offices with computer systems. We are an authorized dealer for the only program now in use by over 80,000 fellow physicians — The Medical Manager. Unique policies offered only by Healthware, Inc include unlimited free training for all current and future employees to maximize your office productivity; lifetime free software support available 24 hours a day; a written guarantee that your cash flow will increase by more than the payment for the system or we will refund the difference. For further details or to see the system, please stop by our booth today.

HOECHST-Roussel Pharmaceuticals Inc **#325**
Route 202-206, PO Box 2500
Somerville, NJ 08876
(908) 719-5876
We cordially invite you to visit our exhibit where our top sales representatives will welcome the opportunity to discuss our products with you. Featured will be Trental® (pentoxifylline), the only proven effective agent for the treatment of intermittent claudication; DiaBeta® (glyburide), the world's most prescribed oral hypoglycemic; Claforan® (cefotaxime sodium), a third generation cephalosporin which has a twelve-year history of excellence based on efficacy, safety and cost effectiveness; and Altace™ (ramipril), a long-acting ACE-Inhibitor indicated for the treatment of hypertension. Altace™ is jointly marketed by Hoechst-Roussel Pharmaceuticals Inc and The Upjohn Company.

Holdaway Medical Services **#409**
11400 Bluegrass Pkwy
Louisville, KY 40299
(502) 266-0092
Holdaway Medical Services is a diversified health care service company that dedicates itself to maintaining the best in customer service and satisfaction. HMS services: cardiopulmonary for home care, nursing home and hospitals. Long term care division: consultant services, D.O.N. support/training. Rehab/specialty seating: pediatrics, adults, custom, planar seating-power equipment-service. Home Infusion: parenteral nutrition — pain management — anti-infection therapy — chemotherapy. Durable Medical Equipment: ambulatory, arthritic, bathroom and bed accessories — diabetic management — orthopedic, ostomy, urologist, exercise equipment.

Homedco **#230**
11001 Bluegrass Pkwy, Suite 380
Louisville, KY 40299
(502) 267-9671
Homedco is one of the largest home infusion/enteral and respiratory/durable medical equipment providers in the nation. We have four branches which service Kentucky. We will be exhibiting the latest technology and services in these areas of home care. On display will be HomedNet, a computerized communication, information and formulation system for home Total Parenteral Nutrition patient management.

Image Technology, Inc **#228**
PO Box 21844
Lexington, KY 40522
(606) 263-7777

Ispec, Incorporated **#118**
113 Etter Lane
Georgetown, KY 40324
1-800-284-8384
Ispec, Inc is a local medical company specializing in the sale of refurbished medical equipment and offers full biomedical services. With over forty-one years combined experience in the medical field, Ispec is truly a unique entity. All equipment sold is contingent upon physician approval and comes with full warranties. Ispec's goal is to save the buyer 50-60% of the cost of new equipment while not sacrificing quality.

J.B. Lippincott Company **#300**
227 E Washington Square
Philadelphia, PA 19106-3780

Jefferson Hospital **#205**
2700 River City Park Road
Jeffersonville IN 47130
(812) 284-3400

Jewish Hospital HealthCare Services **#401A**
217 East Chestnut St
Louisville, KY 40202-1886
(502) 587-4914
Private practice physicians are facing a radically different health care environment. Jewish Hospital's Physician/Hospital Development Department offers a comprehensive program to help physicians build their private practice and manage it more effectively. Some of the services provided to physicians include: associate recruitment, practice management services, community education and involvement, office staff seminars, market surveys, and patient demographic information. Material will be available describing private practice enhancement programs.

Kentucky Air National Guard **#329**
1019 Old Grade Lane
Louisville, KY 40213-2623
(502) 364-9424
The Kentucky Air National Guard is a Reserve Component of the Air Force. It offers physicians and other medical professionals the opportunity to serve their state and nation in a unique way. Many doctors train to be flight surgeons, which gives them the chance to do something interesting that no other part time career can offer. You also receive good pay, benefits, retirement and other valuable training that will enhance your current career.

Kentucky Army National Guard **#319**
Boone National Guard Center
Frankfort, KY 40601-6168
1-800-372-7601
Today the mission of the Army National Guard is a dual one, state and federal. It offers physicians and other medical professionals the opportunity to serve their state and nation in a unique way. Many doctors train to be flight surgeons, battalion sur-

geons, general medical officers and other specialties, which gives the opportunities that no other part-time career can. You also receive good pay, benefits, retirement, and other valuable training that will enhance your career. The Kentucky Army National Guard Recruiting Team will be available to answer any questions and give out literature. Stop in and see us or give us a call.

Kentucky Medical Insurance Company/ United Leasing, Inc **#114 &116**
303 N Hurstbourne Pkwy
Louisville, KY 40222-5143
(502) 339-5736
Established by the Kentucky Medical Association (KMA) during the insurance cirsis of the mid-70's to give physicians more control over their own destiny. Our directive from the KMA was simple: provide adequate prices, maintain financial strength, and don't bail out when times are tough. United Leasing can provide medical equipment, office equipment and vehicles at affordable rates. Services Available: Professional Liability, Leasing, KMIC Retirement Trust, KMA Agency, Hospital Division. Service Area: All of Kentucky

Kentucky Medical Review Organization **#102**
10503 Timberwood Circle, Suite 200
Louisville, KY 40223
(502) 339-7442
Kentucky Medical Review Organization is the Kentucky physician-directed Peer Review Organization (PRO) that contracts with the Federal Government to oversee the Medicare program. PROs review health care services funded by Medicare and determine whether those services are reasonable, medically necessary, rendered in the appropriate setting, and of good quality.

Kentucky Organ Donor Affiliates **#428**
305 W Broadway, Suite 316
Louisville, KY 40202
(502) 581-9511
The Kentucky Organ Donor Affiliates is the federally certified organ procurement agency for the state of Kentucky. At the booth, information will be available regarding the physician's role in the donation process, as well as information about the steps required in identifying and referring potential organ and tissue donors. In addition to donation information, there will be materials available to be utilized as guidelines for declaring brain death and information about advance directives.

Kentucky Telco Federal Credit Union **#100A**
3740 Bardstown Road
Louisville, KY 40218
(502) 459-3000
The KMA Credit Union. Offer your staff a fringe benefit that won't cost you a cent! Kentucky Telco is a federal credit union with service centers located in Louisville, Lexington, Owensboro, and Frankfort, all delivering full financial services with federally insured savings, low costs loans, credit cards with no annual fee, Quest ATM services, 24-hour telephone response system, and much more. Kentucky Telco is proud to be the only financial institution endorsed by the Kentucky Medical Assocation.

Key Pharmaceuticals **#435**
2000 Galloping Hill Road
Kenilworth, NJ 07033
(908) 298-4908
Key Pharmaceuticals, a world leader in drug delivery systems, will display the following respiratory and cardiovascular products: Claritin, Vanceril, Nitro-Dur, and K-Dur 20mEq.

Knoll Pharmaceutical Company **#412**
30 North Jefferson Road
Whippany, NJ 07981
(201) 428-4888
Knoll Pharmaceutical Company cordially invites you to visit our booth for information on Isoptin SR (verapamil HCl), Vicodin ES (hydrocodone bitartrate (7.5mg Warning: May be habit forming) and acetaminophen 750mg for moderate to moderately severe pain, and Zostrix (capsaicin 0.025%) for management of arthritis pain.

Lederle Laboratories **#301**
One Cyanamid Plaza
Wayne, NJ 07470
(201) 831-4422
You are cordially invited to visit the Lederle Laboratories booth where we would be pleased to discuss Verelan®, Suprax®, Prostep™, Pipracil® and the Biological products with you.

Lincoln Trail Hospital **#234**
3909 South Wilson Road
Radcliff, KY 40160
(502) 351-9444

Marion Merrell Dow, Inc **#233 & 235**
9300 Ward Pkwy
Kansas City, MO 64114
(816) 966-4000
Headquartered in Kansas City, MO, Marion Merrell Dow Inc manufacturers and markets prescription and over-the-counter pharmaceuticals in North America, Europe, and the Pacific Basin. The company's current prescription product emphasis is in the cardiovascular, respiratory, CNS and gastrointestinal areas.

Mark Kidd Studios of Kentucky **#308**
125 Clay Ave
Lexington, KY 40502
(606) 254-1095

Mead Johnson Nutritionals **#313**
2400 W Lloyd Expressway
Evansville, IN 47721-0001
(812) 429-5000
We cordially invite you to visit our exhibit to meet our representatives who welcome the opportunity to discuss products and services of interest to you. Featured will be Enfamil, Lactofree, Nutramigen, Poly-Vi-Flor, ProSoBee, Tempra.

Mead Johnson Pharmaceuticals **#216**
PO Box 4500
Princeton, NJ 08543-4500
(609) 897-3747
We cordially invite you to visit our exhibit to meet our representatives who welcome the opportunity to discuss products and services of interest to you. Featured will be Buspar (buspirone HC1), and Monopril (fosinopril sodium).

Medic Computer Systems **#103**
8601 Six Forks Road, Suite 300
Raleigh, NC 27615
(919) 847-8102
Complete office management system, consisting of both hardware and software.

Medical Management Consultants, Inc **#406**
204 Meridian Ave
Louisville, KY 40207
(502) 895-6262
Medical Management Consultants, Inc, can submit your claims electronically for faster, easier payment and solve your insurance problems as we have for others in Kentucky since 1980. We cut your red tape and allow you to do what you do best — practice medicine.

Medical Management Resources, Inc **#211**
10200 Linn Station Road, Suite 270
Louisville, KY 40223
(502) 423-5999
Medical Management Resources Inc was founded in 1980 as a pioneer in electronic claims processing (EMC). Today it is a company that has advanced beyond EMC into one that has created a total electronic environment. Medical Management Resources specializes in electronic exchange of information between healthcare providers, healthcare payors, and financial institutions. Services available are: EMC, practice management consulting and education seminars. All are adapted to a single provider as well as large healthcare facilities. For more information call Medical Management Resources Inc at (502) 423-5999.

The Medical Protective Company **#225**
5814 Reed Road
Ft Wayne, IN 46835
(219) 485-9622
The Medical Protective Company continues to provide unsurpassed protection to physicians and dentists exclusively since 1899.

Merck Human Health Division **#407**
22 Silver Ave
Fort Mitchell, KY 41017
(606) 331-5424

Metropolitan Reference Laboratories Inc **#433**
2320 Schuetz Road
St. Louis, MO 63146
(314) 991-1311
Metropolitan Reference Laboratories, Inc (METRO) is a full service clinical laboratory dedicated to excellence of performance in all disciplines of laboratory medicine. METRO is one of the numerous Corning Clinical Laboratories strategically located in major metropolitan areas. Our primary goal is to provide exceptional service to clients in our region. Directed by Board Certified Pathologists and PHD level scientists, the laboratory is equipped with state-of-the-art instrumentation and staffed by experienced Supervisors, Technologists and Cytotechnologists. At METRO, our primary focus is on quality . . . quality in testing . . . and quality in data handling and reporting. METRO is fully accredited by the Department of Health and Human Services which provides authorization to participate in interstate commerce, by Medicare, and the College of American Pathologists.

Miles Inc Pharmaceutical Division **#434**
PO Box 20399
Louisville, KY 40250
(502) 499-8312

Mosby/Churchill/Waverly **#402**
17212 Little Eagle Creek Ave
Westfield, IN 46074
1-800-383-9166
The world's largest medical publisher, MCW is a joint venture of Mosby, Churchill Livingstone, William & Wilkins, and Lea & Febiger. We also offer Thieme, McGraw-Hill, and are the exclusive source of ImageDisc and JCAHO products. Stop by to see the latest books, journals, software, and laser discs, covering all medical specialties.

National Health Laboratories **#126**
4500 Conaem Drive
Louisville, KY 40213
(502) 456-4700

Olsten HealthCare **#427**
710 Executive Park
Louisville, KY 40207
(502) 895-4213
Olsten has offered home health care services for more than 20 years. Our network of 250 offices across the US and Canada provides a range of experienced health-care professionals from companions to registered nurses, therapists and medical social workers. We've developed a staffing service that institutions, clinics or physician's offices can depend on to meet their staffing needs on a short-term, temporary basis when experiencing a shortage of staff. Confirming it's commitment to quality, Olsten is the first international home care and staffing service company to seek accreditation through JCAHO.

Ortho Pharmaceutical Corporation **#101**
Route 202
Raritan, NJ 08869
(908) 218-6943
Visit the Ortho Pharmaceutical exhibit where representatives are prepared to discuss products and educational services of interest. Featured products include Ortho's oral contraceptives, ORTHO-CEPT™, (desogestrel/ethinyl estradiol), ORTHO TRI-CYCLEN™ and ORTHO-CYCLEN® (norgestimate/ethinyl estradiol). Desogestrel and norgestimate are the first new progestins in the United States in over 20 years. Also featured are the most frequently prescribed vaginal antifungal, TERAZOL®, and the broad-spectrum quinolone antibiotic, FLOXIN®.

Our Lady of Peace Hospital **#424**
2020 Newburg Road
Louisville, KY 40232
(502) 451-3330
Our Lady of Peace Hospital treats persons with emotional, behavioral, psychiatric and addiction disorders. We offer short-term acute care programs for children, adolescents and adults. Treatment options include inpatient, partial hospitalization (day treatment) and intensive outpatient programs (evenings), as well as a full range of outpatient counseling services available at seven Peace Counseling Center locations. Come by our booth and see how, for forty years, Peace has been helping to heal the whole person: mind, body and spirit.

Parke-Davis **#121**
201 Tabor Road
Morris Plains, NJ 07950
(201) 540-2845

P.C. Products **#209**
800 Exmoor Ave
Louisville, KY 40223
(502) 244-7165
Seller of phlebotomy wall stations which organizes blood drawing supplies into a space-saving area within reach of the phlebotomist while drawing the patient. Supplies are kept above and away from possible cross contamination by blood borne pathogens. Also available are Portabull® containers for safe and secure transport of specimens to the laboratory.

Pfizer Labs **#305**
14402 Willow Grove Circle
Louisville, KY 40245
(502) 244-7124
Pfizer Labs manufactures and markets both Norvasc (amlodipine bestlate) and Zithromax (azithromycin).

Physicians Financial Services, Inc **#112**
7400 LaGrange Road #304
Louisville, KY 40222
(502) 426-8833
Physicians Financial Services, Inc works with physicians in all areas of financial plan-

ning and estate planning. You will want to stop by and request information on the KMA endorsed Disability Income Insurance Plan. The premium discounts negotiated by your association makes this the lowest plan available with exceptional benefits and legal definitions.

The PIE Mutual Insurance Company **#416**
9300 Shelbyville Road, Suite 1001
Louisville, KY 40222
(502) 339-7431 or 1-800-228-7431
The PIE Mutual Insurance Company of Cleveland, Ohio offers Kentucky physicians the advantages of an insurance program that has made it the leading professional liability carrier in Ohio. Owned and controlled by policyholders, the PIE is a nonprofit company whose innovative program features claims handling by a specialty law firm, physician participation in all areas of operations including peer review of all applicants, and rate stability that rewards loss-free physicians with scheduled premium reductions.

Pratt Pharmaceuticals Pfizer, Inc **#310**
3609 Locust Circle E
Prospect, KY 40059
(502) 228-6345

Princeton Pharmaceutical Products **#125**
PO Box 4500
Princeton, NJ 08543-4500
(609) 897-3747
We cordially invite you to visit our exhibit to meet our representatives who welcome the opportunity to discuss products and services of interest to you. Featured will be Capoten (captopril tablets), Duricef (cefadroxil), and Pravachol (pravastatin sodium).

RANAC Computer Corporation **#335**
3703 Taylorsville Road #217
Louisville, KY 40220
(502) 473-0518
CompreMED™ is a total medical practice management system. Software modules can be customized to meet requirements of small practices or large clinics; includes electronic transmission of claims; electronic posting of payments; patient information; A/R management; billing; practice analysis; practice marketing; clinical & medical records; appointment scheduler; and letter writer. Available on IBM PS/2 and IBM compatibles.

Ransdell Surgical, Inc **#212**
752 Barret Ave
Louisville, KY 40204
(502) 584-6311
Ransdell Surgical, Inc is a full line med/surg distributor servicing Kentucky and Southern Indiana. Ransdell Surgical, Inc provides not only the right products, but the value added services that our customers have requested.

RCFA Physician Managers **#309**
9724 Kingston Pike, Suite 1200
Knoxville, TN 37922
(615) 531-0176
Practice management consultants for physicians.

Reed & Carnrick Pharmaceuticals **#127**
257 Cornelison Ave
Jersey City, NJ 07302
(201) 434-4000
Serving the medical profession for over 100 years, Reed & Carnrick Pharmaceuticals has established itself with a line of quality medications which are held in high regard in the areas of gastroenterology, proctology, cardiology, and dermatology. Reed & Carnrick is proud to present *ACTINEX* (Masoprocol Cream) 10% the first new agent for Actinic Keratosis in over 20 years. In addition, COLYTE-FLAVORED (PEG-3350 & Electrolytes) for Oral Solution, is the only truly flavored PEG Lavage. Stop by and find out why physicians have prescribed Reed & Carnrick products for so many years. Colyte, Cortifoam, Dilatrate-SR, Durascreen SPF-15, Epifoam, Levatol, Phazyme Drops, Phazyme-95, Phazyme-125, Phazyme Chewables, Proctocream-HC, Proctofoam-HC, Proctofoam-NS, R & C Lice Treatments.

Republic Bank & Trust Company **#229**
601 W Market St
Louisville, KY 40202-2700
(502) 584-3600
As the only bank endorsed by the Jefferson County Medical Society, Republic Bank & Trust Company is committed to offering products and services that accommodate a physician's diverse financial needs. During KMA we will have information available on 100% Mortgage Financing, as well as the preferred Client Services program and the Republic Advantage Account. Republic Bank & Trust Company's products and services make banking easy and convenient and offer you the advantage of local service.

Rhone-Poulenc Rorer Pharmaceutical, Inc **#408**
500 Arcola Road, 4B10
Collegeville, PA 19426
(215) 454-8000
Rhone-Poulenc Rorer Pharmaceuticals Inc invites you to visit our booth where our representatives will be happy to discuss Lovenox® (enoxaparin), Dilacor XR® (diltiazem HCl), and Nitrolingual Spray® (nitroglycerin lingual aerosol).

Roche Biomedical Laboratories, Inc **#415**
6370 Wilcox Road
Dublin, OH 43017
(614) 889-1061
Medical Laboratory reference testing services.

Roche Laboratories **#410**
340 Kingsland St
Nutley, NJ 07110
(201) 235-5000
The people of Roche Laboratories invite you to visit our exhibit where we will be glad to discuss any questions or issues related to our products.

Roerig Division of Pfizer, Inc **#334**
235 East 42nd St
New York, NY 10017
(212) 573-2323

Ross Laboratories **#200**
825 Washington St
Shelbyville, KY 40066-0577
(502) 633-3637
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Louisville, KY 40202
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United States Army Medical Department **#117**
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Falls Church, VA 22041-3258
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Lakeview Rehabilitation Hospital #133
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Lakeview Rehabilitation Hospital in Elizabethtown, KY is a 40-bed comprehensive rehab facility providing services on an inpatient and outpatient basis. Opening in November 1987, we have specialized in rehabilitation providing a full range of programs for a wide variety of physical conditions such as stroke, head trauma, orthopedic and back problems, work-related injuries, hip fractures, spinal cord injuries, and pulmonary and neurological disorders. Our hospital is solely dedicated to rehabilitation and is specifically designed with special attention to accessibility for the disabled.

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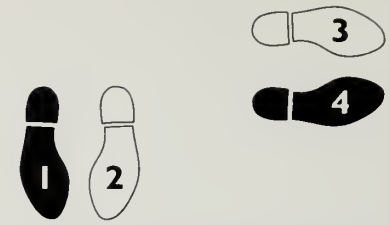


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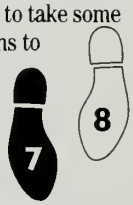


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Physician leaders will benefit by:

- Learning how to hone their leadership skills
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American Medical Association
Physicians dedicated to the health of America

Robert R. Goodin, MD Nominated for KMA President-Elect

Robert R. Goodin, MD, has been nominated by the Jefferson County Medical Society for the office of President-Elect of the Kentucky Medical Association.

A highly respected cardiologist, Dr Goodin has been dedicated in his nurturance of organized medicine. In 1981-82 he served as president of the Jefferson County Medical Society. From 1986 until 1990 he served as a KMA alternate delegate to the AMA House of Delegates, and has served as a KMA delegate to the AMA since 1991. Dr Goodin has chaired several KMA committees including Changing Trends in Medicine and Faculty Practice, and currently chairs the Physician Manpower Committee and is a member of the Continuing Medical Education Committee. This year he became a member of the American Medical Association Continuing Medical Education Advisory Committee.

Dr Goodin cites his primary interests in medicine as:

- enhancing primary care and rural health care access
- medical education
- physician involvement in health system reform

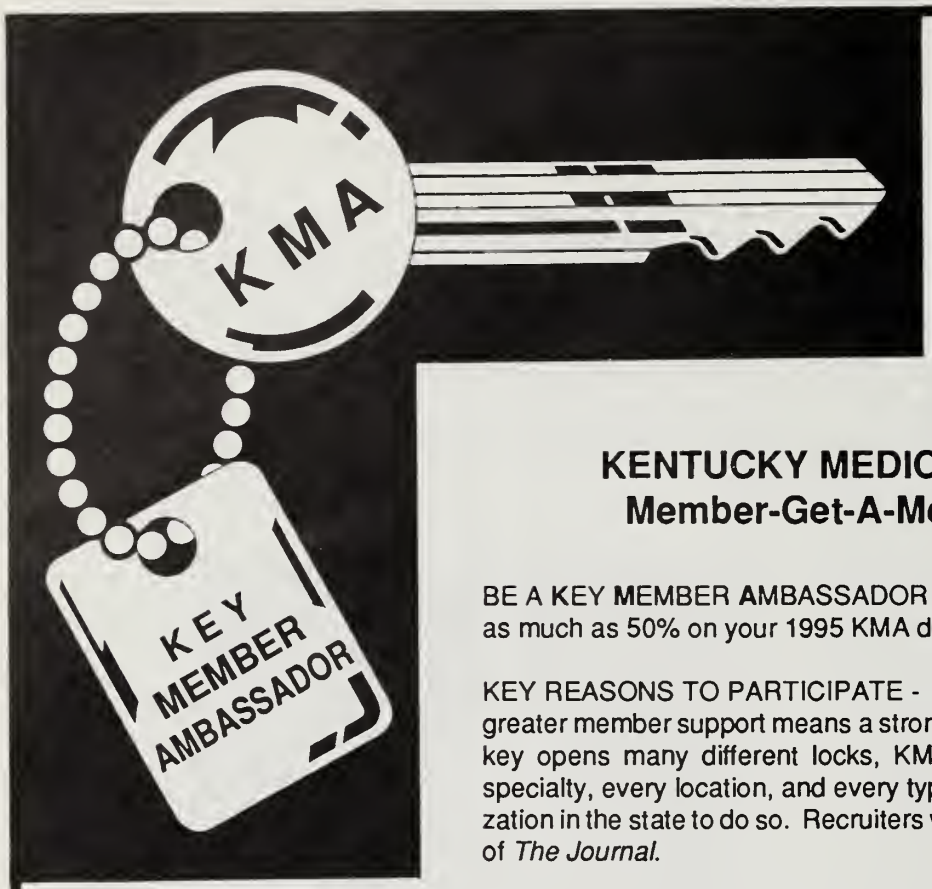
A native of Adair County, Kentucky, Dr Goodin received his undergraduate degree from the University of Kentucky in 1960 and is a 1964 graduate of the University of Louisville Medical School, where he was senior class president and valedictorian.

Following completion of an internship and residency at Barnes Hospital, Washington University in St Louis, Dr Goodin earned a



cardiology fellowship at Emory University, 1968-70. He served on the faculty of the University of Louisville Medical School from 1970 to 1974 and continues service there as a clinical professor of medicine. In 1974 he began private practice with Cardiovascular Associates and is currently senior physician of the 17 cardiologists in that group.

Dr Goodin and his wife, Carol Ann, have three children and reside in Louisville. KMA



YOU are the KEY to the

KENTUCKY MEDICAL ASSOCIATION
Member-Get-A-Member Campaign

BE A KEY MEMBER AMBASSADOR - and unlock the opportunity to save as much as 50% on your 1995 KMA dues!

KEY REASONS TO PARTICIPATE - Besides the dues incentive to you. . . greater member support means a stronger, more unified, voice. As a master key opens many different locks, KMA represents physicians from every specialty, every location, and every type of practice - and is the only organization in the state to do so. Recruiters will also be recognized in future issues of *The Journal.*

KEY PROSPECTS - New physicians in your area, hospital staff colleagues, alumni from your medical school, physicians in your specialty, or nonmembers in a particular target group, eg, women physicians, faculty, international medical graduates - take your pick.

KEY TO RECRUITMENT - The most effective way to recruit new members is through a **personal** conversation or note conveying your own thoughts about why you are a member. Special recruiter kits containing brochures and information on benefits are available for your use.

- OPEN THE DOOR FOR DUES DISCOUNTS -

The campaign targets1994 membership. As a KMA Key Member Ambassador, the credit you earn for any new member joining before **April 1, 1994,** will be applied to your 1995 KMA dues. You hold the KEY to the amount of the discount:

Recruit				KMA Dues Discount
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YES, I'm interested in the Member-Get-A-Member campaign. Send me a recruiter kit.

Name _____

Address _____

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I'd like a list of potential members:

- ❒ In my county
- ❒ In my specialty
- ❒ From my medical school class
- ❒ Faculty at my school
- ❒ Women
- ❒ International medical graduates

Mail to: *KMA Membership Dept., 301 N. Hurstbourne Pky, #200, Louisville, KY 40222-8512. Or call, (502) 426-6200.*

RATES AND DATA

All orders for classified advertising must be placed in writing and will be subject to approval by the Editorial Board. The right is reserved to decline or withdraw advertisements at the publisher's discretion.

Deadline: First day of month prior to month of publication.

Word count: Count as one word all single words, two initials of a name, single numbers or groups of numbers, hyphenated words, and abbreviations.

Rates to KMA members: $10 per insertion up to 50 words, 25¢ each additional word. To non-members; $30 per insertion up to 50 words, 25¢ each additional word.

Send advance payment with order to: The Journal of KMA, 301 N Hurstbourne Pky, Ste 200, Louisville, KY 40222.

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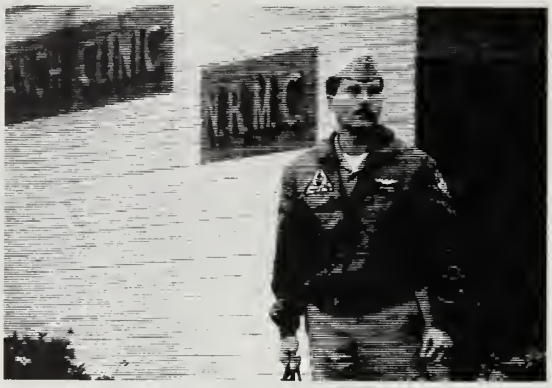
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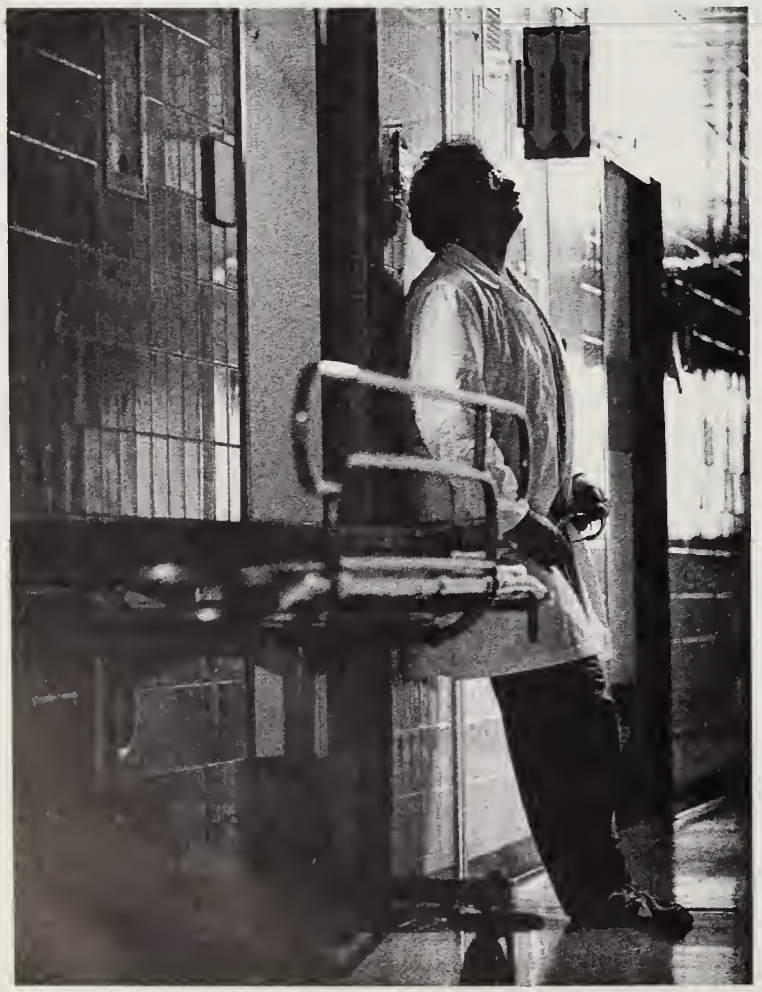
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Dr. Kevin Fullin, Cardiologist, Kenosha, Wisconsin,
Member, American Medical Association

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While others were content to downplay the issue of family violence, Dr. Fullin would not. He petitioned state officials, and through his efforts the first Domestic Violence Advocate Program in his state was created.

"Organized medicine must serve as an advocate for patients," stressed Dr. Fullin.

The American Medical Association (AMA) couldn't agree more. We're committed to focusing physician attention on the issue of family violence.

Become a member of the AMA today.

Members of the AMA are encouraged to join their state, county and specialty societies.

American Medical Association

Physicians dedicated to the health of America

SEPTEMBER

11-14 — The Decade of the Brain: An International Conference; The Omni-Shoreham, Washington, DC. CME — 28 Credit Hours, AMA Category 1. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Street, NW, Washington, DC 20037; 202/994-4285, FAX 202/994-1791.

18 — Tenth Annual Ophthalmology Seminar: Update on Management of Age-Related Macular Degeneration; Humana Hospital Audubon, Louisville, KY. Contact: Cathy Edens, 240 Audubon Medical Plaza, Louisville, KY 40217; 502/636-2823.

OCTOBER

1-3 — International Liver Symposium: Marriott Crystal Gateway Hotel, Arlington, VA. Contact: Daniel E. Reichard, George Washington University Medical Center, Office of CME, 2300 K St, NW, Washington, DC 20037; 202/994-4285, FAX 202/994-1791.

9-13 — Gastroenterology Board Review Course; Marriott Crystal Gateway Hotel, Arlington, VA. Contact: Daniel E. Reichard, George Washington University Medical Center, Office of CME, 2300 K St, NW, Washington, DC 20037; 202/994-4285; FAX 202/994-1791.

9-13 — Medical Oncology Board Review Course: Ritz-Carlton, Pentagon City, VA. Contact: John F. Vargo, George Washington University Medical Center, Office of CME, 2300 K Steet, NW, Washington, DC 20037; 202/994-4285; FAX 202/994-1791.

13-17 — The American Society of Internal Medicine 37th Annual Meeting; J. W. Marriott Hotel, Washington DC. Contact: Melinda Klein; 202/835-2746, ext 266.

28-31 — 87th Annual Scientific Assembly of the Southern Medical Association; New Orleans, LA. Contact: SMA Registration Dept; 205/945-1840, 800/423-4992 or FAX 205/942-0642.

31-Nov 5 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

NOVEMBER

14-18 — 97th Annual Meeting of the American Academy of Ophthalmology; McCormick Place, Chicago. Contact: The American Academy of Ophthalmology, Meetings Department, PO Box 7424, San Francisco, CA 94120-7424; 415/561-8500.

1994

FEBRUARY

6-10 — Southeastern Surgical Congress; Buena Vista Palace, Lake Buena Vista, Florida. Contact: the Congress Office, Suite 410N, 1776 Peachtree St, Atlanta, Ga 30309; 404/607-8958.

Make Your Reservations Now

It is important that you begin to make your room reservations as soon as possible for the KMA Annual Meeting, September 27-30. The Hyatt Regency Louisville will be the Headquarters Hotel (Phone 502/587-3434). In making your reservations, remember the first House of Delegates meeting will be Monday, September 27. Be sure and identify yourself as a KMA meeting attendee to receive the special convention rate — Single — $71/Double — $81.

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Please notify us at least two months in advance.

Send new address to:

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301 N Hurstbourne Pkwy, Suite 200
Louisville, KY 40222-8512

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs. During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli,* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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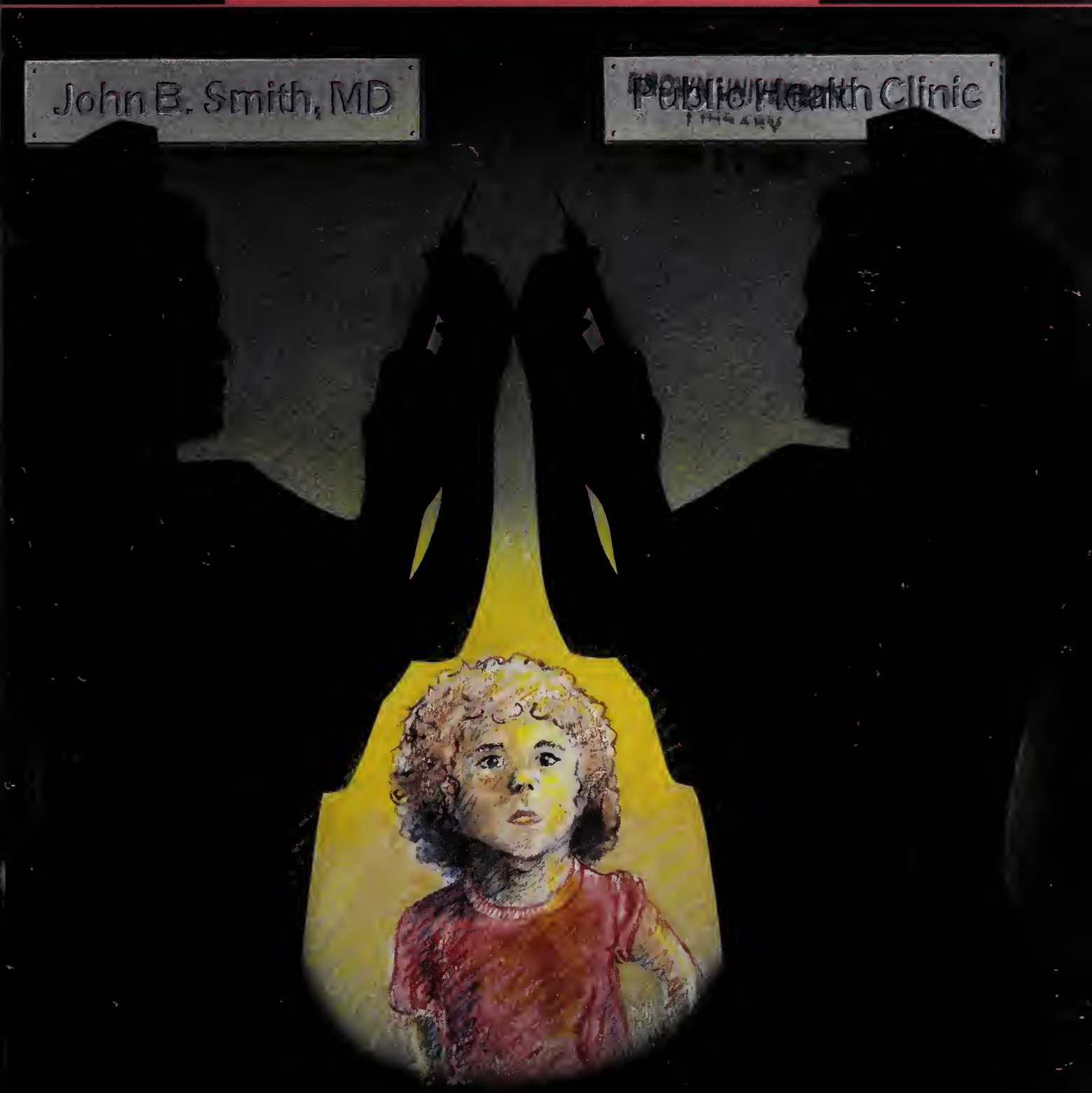
Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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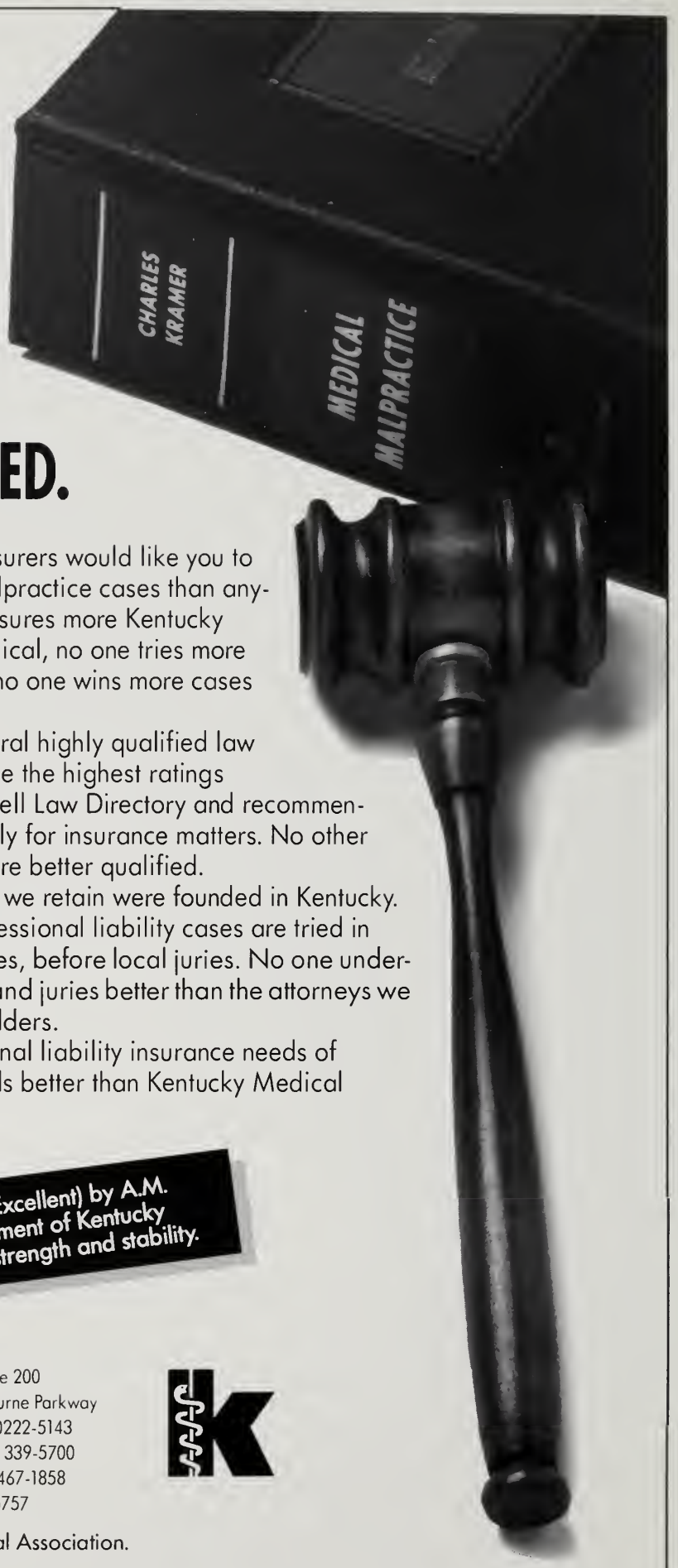
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JOURNAL OF THE
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Childhood Immunization

SEPTEMBER 1993
VOLUME 91 NUMBER 9



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***COVER:** Whether immunizotions ore odministered by the health department or primory physicion does not seem to be the concern of our cover child — the method hos her ottention. This memory-evoking ortwork by Lee Wode of Louisville introduces on orticle on page 394.*

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William B. Monnig, MD

The Privilege of the Power of the Office

As the associational year comes to a close, I again have the opportunity to address you, the physicians of the Kentucky Medical Association. There is no way to adequately thank each of you for allowing me to serve as President of the Kentucky Medical Association. It is an honor that no particular one deserves and one that can be bestowed on only a limited number of the physicians who believe in and act on behalf of the Association. Thank you for the privilege of experiencing the power and authority that have become inherently associated with the title and position.

The title of President of the KMA allows that person (me, this year) to speak with an authority and political clout that far exceeds the individual's personally acquired status. The KMA is an association that is respected throughout the Commonwealth as the organization that codifies the ideals and policies of the practicing physicians of this state. The mantle of authority of the Kentucky Medical Association creates an aura of respect and community standing for the President of the Association as a spokesman on health care issues. Experiencing that inherent respect and authority has been both exhilarating and humbling for me. Again, thank you for that opportunity.

As many of you are aware, this associational year was an unexpectedly busy one for the KMA leadership. Health care reform dominated our time and efforts, but the usual associational activities were also attended to. The elected officers of the Association all worked overtime to meet the demanding schedule thrust upon us by the governor's insistence on addressing health care system reform in a special legislative session. We engaged in animated debate and reached soul searching conclusions that furthered the policies and positions of the KMA.

"The KMA is an Association that is respected throughout the Commonwealth as the organization that codifies the ideals and policies of the practicing physicians of this state. The mantle of authority of the Kentucky Medical Association creates an aura of respect and community standing for the President of the Association as a spokesman on health care issues."

"... the Kentucky Medical Association is essential to the efforts of physicians to maintain control of our profession and to the efforts to improve the health and well-being of all Kentuckians."

Those positions and policies were forged into a proactive reform package that we advocated. On behalf of the Association I extend my thanks to the officers, Board of Trustees, senior staff, and lobbyists for their efforts. It was again easy to speak on behalf of the Association when so many great minds were working to create the themes, the positions, and the reform proposals.

I also thank all of you who participated in the local medical society and the Trustee Districts. I appreciated the invitation to visit with

"The Association is respected by other health care entities, the news media, the governor's office, the legislature, the business community, and the public at large. It is seen as the body and soul of practicing physicians' beliefs and policies. The KMA is recognized as the collective voice of physician's concerns."

you and apologize if I was unable to fulfill your requests. The efforts of county medical societies played a very important part in establishing the path to be followed by the KMA. Your efforts are greatly appreciated. You exerted your influence; and the effects of your efforts are self evident. I hope each of you will continue your active participation. I feel certain the KMA leadership will remain enthusiastic and supportive of your efforts.

Most of all the KMA represents individual practicing physicians in Kentucky. We try to represent your views. The numerous phone calls and letters were all appreciated. Criticisms were taken to heart and those that offered solutions were read, digested, and discussed with enthusiasm. I greatly appreciated the words of encouragement from across the state.

This year made me realize that physicians, including me, underestimate the stature of the Kentucky Medical Association. The Association is respected by other health care entities, the news media, the governor's office, the legislature, the business community, and the public at large. It is seen as the body and soul of practicing physicians' beliefs and policies. The KMA is recognized as the collective voice of physician's concerns. The KMA is an authority on patient care issues and medical practice. Each physician member by your active participation at the local and state level gives further credence to the public's perception. You have fulfilled my greatest hopes, and I am appreciative. Because of your individual and collective efforts, the KMA has remained an essential player in reforming the health care system.

Again, thank you for allowing me to be President of the KMA; to be your spokesman during such challenging times. When I was successful, it was because I remembered the policies of the Association and the collective wisdom of my fellow leaders. When I was unsuccessful, it was because I failed to remember the policies or heed the advice of the officers and staff around me.

This year again demonstrated that the Kentucky Medical Association is essential to the efforts of physicians to maintain control of our profession and to the efforts to improve the health and well-being of all Kentuckians. The efforts of the Association do not start and stop with the changing of its officers. It has been my pleasure to be President. You have allowed me to savor moments of importance and you have maintained and supported the Association that allowed those moments to occur. I will continue to work for the Association in a less public manner. We are fortunate to have a new President, Dr Ardis Hoven, who has been seasoned by her active participation in the last year. She has already demonstrated her leadership skills, her spokesperson skills, her enthusiasm to pursue KMA objectives. Please give her your time, your effort, your support. Her success as our leader will depend on our collective sustained efforts and cooperation. She deserves our best efforts; and through those efforts, the KMA will continue to flourish.

William B. Monnig, MD
KMA President

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VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

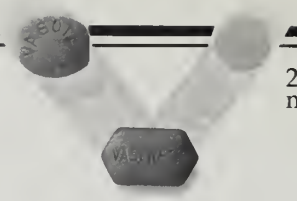
Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality*.



CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General; Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy, Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC® should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5. 6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate; Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent pre-existing renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions: Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide; When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Cholestyramine and colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively. Thiazides may be administered two to four hours before the resin when the two drugs are used concomitantly.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings: Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported. *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction, pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia, atrial fibrillation, hypotension, angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression, a few cases of hemolysis in patients with G-6-PD deficiency have been reported in which a causal relationship to enalapril cannot be excluded; *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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YOCON®
YOHIMBINE HCl

Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

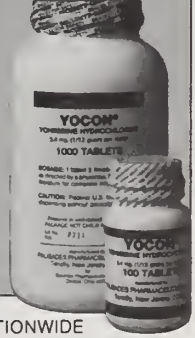
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



References:

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Factors Influencing the Use of Primary Care Physicians and Public Health Departments for Childhood Immunization

Arch G. Mainous III, PhD; William J. Hueston, MD

The purpose of the study was to examine factors influencing the use of primary care physicians and public health departments for childhood immunization for patients in rural and urban areas.

A telephone survey employing probability sampling (random digit dialing) was conducted to obtain data from a sample of adults (≥18 years) living in Kentucky. Data are from 97 households with children under age 5 living in the home. The majority of the respondents (95%) reported that their children had received immunizations. The primary locations for receipt of immunizations were the health department (51%) and a primary care physician's office (37%). Sixty-five percent of those who used the health department for childhood immunizations reported that they did so for financial reasons. Individuals who received immunizations from the health department were more likely than those who received them at a primary care physician's office to have incomes at or below the poverty level and live in a rural area. The results of a logistic regression computed on use of the health department or primary care physician for immunizations indicated rural/urban residence as the only significant predictor, with urban residents 3.7 times more likely than rural residents to receive immunizations from a primary care physician.

These results suggest that many families in rural areas have primary care physicians, but use the health department for their routine childhood immunizations. The results support previous data which indicate that delivery of childhood immunizations by primary care physicians is less available to rural than urban individuals.

In the past decade, childhood immunization rates in the United States have decreased to levels lower than comparable developed countries and many developing countries.[1, 2] Consequently, epidemics of vaccine preventable diseases have occurred.[3, 4]

While the vast majority of children are immunized by the time of enrollment in school,[4] the key to a successful immunization program may hinge on delivery of immunizations on time to preschool aged children. One factor contributing to the decrease in the number of children who receive their immunizations at the proper time is missed opportunities to administer vaccines.[4, 5] Missed opportunities may become increasingly important as larger numbers of primary care physicians no longer offer childhood immunizations in their offices.[6-8] Decreased availability from primary care providers and increasing costs of immunization have forced patients to rely on public health clinics to obtain immunization services.[4] A previous report which discovered that preschool children who were unvaccinated for measles were more likely to receive health care in the public sector raises concerns that public health facilities may not effectively meet current immunization standards.

In a previous study of Kentucky primary care physicians conducted in 1991, we found that rural physicians were less likely than their urban counterparts to offer immunization services to their patients.[8] Rural physicians referred their patients exclusively to public health departments for this service. This study further examines the delivery of childhood immunizations by comparing the primary source of immunization for patients in rural and urban areas. The primary hypothesis for this study is that rural patients will rely more on public sources for their immunizations than urban patients.

Methods

The data are from the 1992 Kentucky Health Survey, an annual probability telephone survey of adult (18 and older) Kentucky residents conducted in June 1992. The survey was an omnibus questionnaire collected by the University of Ken-

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Table 1. Sample Demographic Characteristics (n = 97).

Age, y (mean ± SD)	33 ± 10
Gender	No. (%)
M	39 (40)
F	58 (60)
Race	No. (%)
W	88 (91)
B	8 (8)
Other	1 (1)
Residence (MSA county)	No. (%)
Urban	46 (47)
Rural	51 (53)
Education	No. (%)
< HS	14 (14)
> HS	83 (86)
Poverty Status	No. (%)
at or below Threshold	26 (27)
above Threshold	71 (73)

tucky Survey Research Center. The telephone survey used random-digit dialing with Waksberg clustering.[10] The overall response rate of the survey was 60%, supplying a total sample of 617 individuals. The survey's margin of error is slightly less than ±4 percentage points at the 95% confidence level.

Data for this study are drawn from a subsample of 97 households who had children under age 5 living in the home. The decision to limit questions regarding childhood immunizations to respondents with children under 5 was designed to minimize memory errors. The respondents were asked a series of questions regarding receipt of childhood immunizations, including the location of immunizations. The location for childhood immunizations was initially asked in an open-ended format. If the respondent reported using the health department, each was asked the primary reason for use of the health department. Subsequent analyses of location of immunization were limited to those who received all of their routine immunizations from their primary care physician and those who utilized the health department for some or all of their childhood immunizations.

Households were defined as urban based on whether their county of residence was part of a metropolitan statistical area (MSA), while rural respondents were those who lived in a nonMSA county. Family economic status was classified using the 1990 poverty level threshold. Individuals were classified as being at or below, or above the 1990 poverty threshold.[11] Poverty level threshold was used rather than household income because the poverty level takes into account not only household income but size of family and the number of related children under 18 years of age (eg, the poverty threshold of a four person family with two children under age 18 would be an annual income of $13,254). This measure is appropriate for examining the effect of family economics on health care decisions like childhood immunizations.

Respondent gender was not used in the analyses with location of childhood immunization because of the limited theoretical value of the gender of a proxy respondent as a factor in location of immunization. Additionally, respondent race was not used in analyses regarding use of the health department or a primary care physician's office for childhood immunizations because of the limited number of nonwhite respondents.

Fisher's exact tests were computed for examining the relative independence of the variables in bivariate analyses. In the case of rural/urban residence a one tailed test was computed due to the directional nature of the hypothesis. T-tests were used to evaluate the association of interval level variables (eg, age, education) with use of the health department or a primary care physician's office for childhood immunizations. A forward stepwise logistic regression was computed on use of health department *vs* primary care physician office with the independent variables of age, rural/urban residence, education (years), poverty level, a 4-point Likert-type indicator of quality of care received from their physician,[12] and an indicator of health care access — number of minutes required to reach primary health care.[13] The partial correlation between the significant predictors in the regression model and location of immunization was computed. All analyses were performed with SAS on an IBM mainframe computer, and statistical significance was assessed using an alpha of 0.05.

Results

Demographic characteristics of the respondents are shown in Table 1. The sample is relatively young and more highly educated than the general Kentucky population but otherwise exhibits similar demographic characteristics.[14] Ninety-five percent of these individuals reported that their children had been immunized and 96% knew where the immunizations had been administered. The

primary locations for receipt of immunizations were the health department (51%) and a primary care physician's office (37%). No other location accounted for more than 9% of the responses.

Sixty-five percent of those who used the health department for childhood immunizations reported that they did so for financial reasons. Other reasons for the use of the health department were quite varied.

Compared to those who received childhood immunization exclusively at their physician's office, individuals who received immunizations from the health department were more likely to be at or below the poverty threshold and live in a rural area (Table 2). There was no significant difference in whether one received immunizations from the health department or their physicians office according to age, education, quality of care received from one's physician, and time required to get to primary care.

While a meaningful number of respondents used health departments for childhood immunizations, none of the rural individuals and only 2 (4%) urban individuals reported that they use the health department for their primary health care. No difference in the number who claimed to have primary care physicians was observed between rural and urban respondents (82% *vs* 78%, p = .62).

The results of the stepwise logistic regression on use of the health department or a primary care physician's office for childhood immunization indicated rural/urban residence as the only significant predictor. Urban individuals were 3.7 times more likely than rural individuals to use primary care physicians for childhood immunizations. The partial correlation of rural/urban residence with use of the health department or a primary care physician's office was r = .21 (p = .02).

Table 2. Use of Health Department or Primary Care Physician by Poverty Level and Rural/Urban Residence.

	Health Department	Primary Care Physician	p
Poverty	18 (82%)	4 (18%)	
Above Poverty	29 (49%)	30 (51%)	
			.01
Rural	29 (67%)	14 (33%)	
Urban	18 (47%)	20 (53%)	
			.05

Comment

The results of this study show that residents of rural areas are more likely than urban residents to utilize local health departments for childhood immunizations. This factor seems to exist independent of family affluence, as measured by the federally defined poverty level. Since others have suggested that reliance on public sector sources for childhood immunizations increases the possibility of missed opportunities for childhood immunization,[4] these data suggest that rural children and those below the poverty level are at greater risk for failing to receive immunizations in a timely fashion.[4, 5] These delays in immunization could lead to increases in the rates of preventable childhood infections in rural populations.[15, 16]

Previous studies have demonstrated that private primary care physicians are increasingly curtailing the practice of offering childhood immunizations[7, 8] and that discontinuation of provision of immunizations is more common among rural practitioners.[8] This study provides additional information regarding differences between childhood immunization delivery in rural as compared to urban areas. Problems in the delivery of immunizations in rural areas may be overlooked since the lower population densities of rural populations make epidemics less likely in these areas. However, if the delivery of immunizations in rural areas requires referral and discontinuity of care with the primary care physician, delays in immunizations may occur. Further investigation of immunization behaviors and vaccination delivery in rural areas may be helpful in preventing future epidemics of preventable childhood illnesses in rural areas.

The findings of this study should be interpreted with an awareness of several possible limitations. First, although the sampling design allows for selection of a generalizable statewide sample of adults, by limiting the subjects to those with children under 5 living in the household the sample size experienced a substantial decrease. Consequently, sampling error estimates for the entire sample may not be valid for the investigated subsample. Moreover, although the present use of a telephone survey should not exclude a large proportion of possible respondents, some lower income households may be excluded. As a result, the finding of a substantial proportion of individuals obtaining childhood immunizations from the health department may be a conservative esti-

mate of the number of individuals using the health department. Second, the method relies on proxy reports (ie, parents or caretakers) of immunizations which may suffer from recall error and self-selection bias.[17] However, proxy respondents for child health care issues have been shown to be adequate sources of data on these issues,[18] and we purposely limited the length of time with which an individual would have to recall events in order to minimize any memory errors.

In summary, these results suggest that families in rural areas are just as likely as urban residents to have primary care physicians but are more likely to receive their routine childhood immunizations from the local health department. Factors affecting the selection of public health departments for childhood immunizations may be associated with higher risks for preventable childhood illnesses.[9] As the public sector assumes a greater role as the primary provider of childhood immunizations, more information is needed regarding why patients decide to use public health departments and how this service could be provided more effectively and efficiently.

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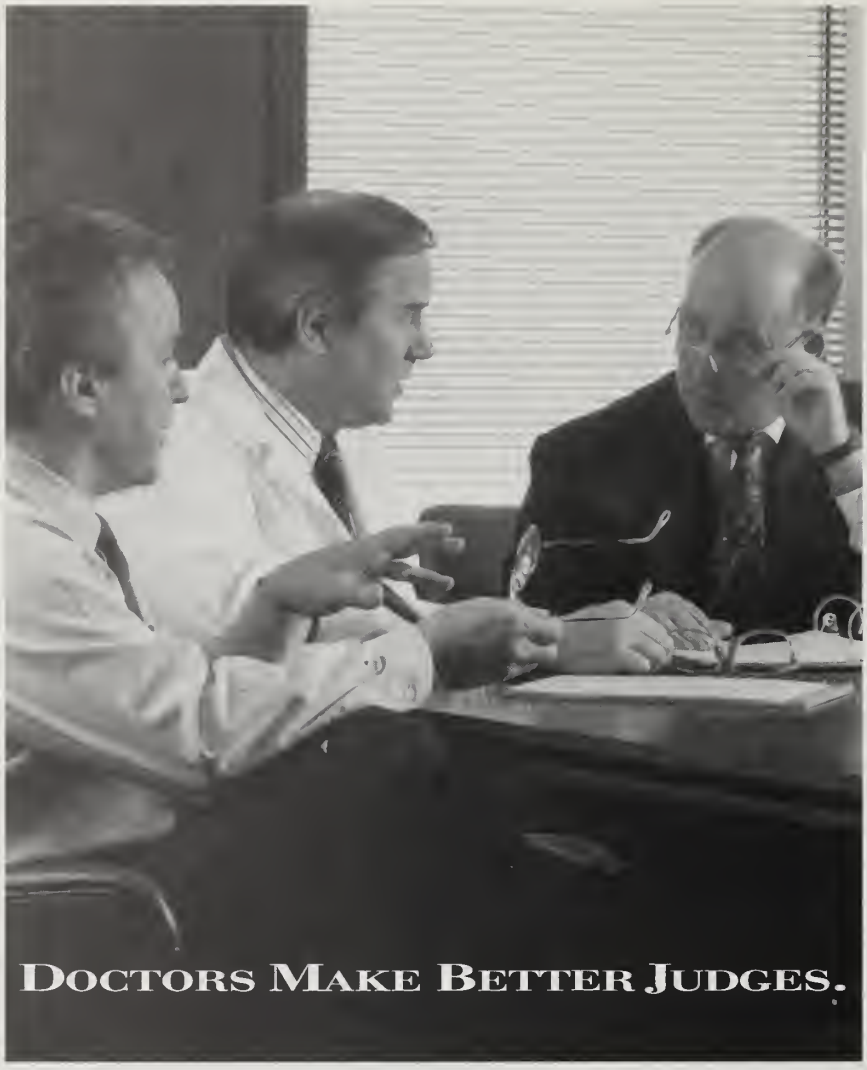
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Apnea of Infancy Associated with Epstein-Barr Virus Infection

Michael W. Simon, MD

The Epstein-Barr virus is one of the most common causes of communicable disease. The clinical manifestations of this virus may vary widely depending on a child's age when primary infection occurs. I describe in this report a child with apnea associated with Epstein-Barr infection.

Apnea is one of the most alarming as well as life-threatening occurrences in childhood. It is significant if there are no spontaneous respirations for 20 seconds or longer. It may occur in neonates and children of all ages. Apnea may occur during sleep, producing changes in skin color and muscle tone. The episode may be terminated by stimulation. Apnea may occur while a child is awake and alert. It may follow choking or vomiting, and produce redness, stiffness, and a scared look. In trying to breath, the child's mouth may be open and the neck may be arched. This may proceed to central apnea with cyanosis, limpness, and unconsciousness.

A number of different conditions may trigger apnea.[1,2] Various infectious processes such as meningitis, pneumonia, sepsis, and RSV infection are well documented etiologies. Disorders of metabolism like hypoglycemia, hyponatremia, hypothermia, and inborn errors of metabolism may induce apneic episodes. Airway abnormalities such as vascular rings, webs, masses, tumors, or malacia of airway structures may present with apnea. Congenital heart disease and cardiac arrhythmias, bacterial toxins and poisons, brain tumors, gastroesophageal reflux, seizures, sedative drug overdose, anemia in the pre-term infant, and disease or abnormalities of the brainstem ventilatory control center may all produce apnea. This article contains a report of a child with an episode of apnea and normal work-up, except for a presumed Epstein-Barr virus infection.

Case Report

The male infant was the 3,300 gram product of a 28-year-old $G_2P_1AB_1$ white female, term by dates and size. The prenatal course was unremarkable. The baby was born by a vaginal delivery with an apgar score of 9 at 1 minute of age and 10 at 5 minutes of age. Resuscitation was unremarkable. He had bruising on the occiput from birth. Mild jaundice developed in the early neonatal course.

The baby was discharged to home in stable condition at 48 hours of age. He was evaluated at 5 days of age and found to be breast-feeding well, thriving, and with resolving jaundice. At 2 weeks and again at 2 months of age he was noted to be growing and developing normally. The baby continued to breast-feed well and had grown to 6,500 grams at the 2-month checkup.

On the child's 95th day of life, he was found in a state of unresponsiveness, clammy, and pale. Respirations were shallow and irregular. He responded to stimulation and appeared normal on evaluation in the emergency room. His vital signs were stable and his oximeter reading was 100% on room air. His temperature was normal.

He was admitted for evaluation of a presumed apneic episode. Admission laboratory studies included a complete blood count with a white cell count of 14,600; hematocrit, 36; differential had 13% neutrophils, 3% bands, 76% lymphocytes, 6% monocytes, 1% eosinophil, and 1% basophil. Urinalysis was normal. Chemistries included a glucose of 90; BUN, 8; sodium, 138; potassium, 6.1; chloride, 106; CO_2, 23; creatinine, 0.3; uric acid, 7.8; inorganic phosphorus, 6.5; calcium, 11.3; alkaline phosphatase, 241; SGOT, 42; LDH, 1116; SGPT, 25; total protein, 7.3; albumin, 5.1; total bilirubin, 0.5; cholesterol, 159; triglyceride, 95. EKG, chest x-ray, and echocardiogram were normal for age. The EEG showed no abnormalities. A pneumogram showed rare pauses in respiration of central origin all less than 8 seconds. He had 2.2% periodic breathing and no airway obstructive events, bradycardia, or tachycardia were noted. There were no desaturations suggesting cyanosis on oximetry. The pH channel

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Table 1. EBV Profile Results

	Admission		Fallaw-up
	Mather	*Baby*	Baby
VCA-IgG (pasitive > 1.00)	5.19	1.69	5.23
EA-IgG (pasitive >1:20)	<1:20	<1:20	<1:20
NA (pasitive > 1.00)	9.44	5.43	9.06
VCA-IgM (positive > 0.4)	Negative	Negative	0.5

Test performed by Rache Biachemical Labarataries.

showed no reflux. Blood and urine cultures were negative for growth. The baby had no additional episodes while in the hospital. EBV profile results were obtained on both mother and child (Table 1). A repeat profile performed on the baby 3 weeks later is also shown in Table 1. He was discharged to home in stable condition before first EBV profile results were known. The baby continues to do well at routine follow-up.

Discussion

The child in this report appears to have had an apneic episode. The admission exam was remarkable only for a red throat. The initial EBV profile was positive for VCA IgG and NA in both the mother and baby. In the mother's case this could be due to a convalescent or old infection. Passively acquired IgG antibody for the baby would be about 1/16 that of the mother, going through four half-lives since birth. The baby's first VCA IgG is not that much lower when compared to mother's level. This would suggest active antibody production in the baby.

The second test, performed on the baby 3 weeks after the first profile, was positive for VCA IgG, NA and VCA IgM. The VCA IgM and NA were higher than the initial results. The EA was negative, and may be negative in 30% of all EBV infections.[3] These results are consistent with the child being in the convalescent phase of EBV illness. This suggests a very short acute phase, which is possible for younger children.

The incubation period of Epstein-Barr virus ranges from 14-60 days.[4-6] Shorter incubation times occur in younger children. The clinical presentation may vary greatly with infection producing mild or inapparent illness, or typical features of EBV illness. The severity of the symptoms is age related. Preschool and young school age children may have no symptoms or only a mild febrile illness with adenopathy.[5-7] Children 3 to 4 years of age may have severe URI, cough, rhinitis, exudative pharyngitis, periorbital swelling, and palpable anterior and posterior cervical nodes. Their symptoms are generally less typical, noted to be milder and of shorter duration when compared to illness in older children.[6]

Diagnosis of Epstein-Barr virus is based on clinical manifestations and laboratory studies.[8, 9] The peripheral blood smear showing atypical lymphocytes and heterophile test have been the standard laboratory detection methods. More recently testing of blood for antibody specific for EBV antigen has been developed. This makes it possible to identify the particular stage of EBV illness. Specific antibody testing may make it possible to identify EBV infection in children younger than 6 months of age and may show EBV to be associated with other illnesses in this age group.

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Management of Patients with the Zollinger-Ellison Syndrome

Frank W. Mocek, MD; Ronald Richardson, MD; Russell Williams, MD; J. David Richardson, MD

The Zollinger-Ellison syndrome, which is due to the secretion of gastrin from non-beta islet cell tumors of the pancreas, results in gastric hypersecretion and severe peptic ulcer disease. In the 1970s H_2 blockers became the mainstay of therapy. More recent evidence indicates that early surgical intervention aimed at tumor extirpation results in improved outcome. The purpose of this paper is to report the case histories of three patients with Zollinger-Ellison syndrome and to review the current literature on management of patients with this syndrome.

In 1955 Zollinger and Ellison described two patients who had the clinical triad of gastric hypersecretion, severe peptic ulcer disease, and non-beta islet cell tumors of the pancreas.[1] They suggested that the condition was mediated by a circulating hormonal substance, which was confirmed in 1960 when Gregory et al[2] extracted gastrin from the tumors.

For more than 20 years after being described, the Zollinger-Ellison (ZE) syndrome (ZES) was seen as being a condition which, if not treated by total gastric resection, would result in early death secondary to the complications of the ulcer diathesis. Because the majority of patients did not live long, management of the gastrinoma was not a focal point of therapy. However, in the 1970s, with the introduction of H_2 receptor antagonists, therapy for ZES has evolved toward medical management and the indications for operative intervention have changed.

The following three cases illustrate the natural history of the ZES.

Patients

Patient 1. Initially, a 64-year-old man presented with a 1-week history of nausea, vomiting, and upper abdominal pain that was described as constant, with occasional exacerbations. He also reported a prolonged history of diarrhea and had lost 50 pounds. The patient's physician obtained an abdominal computerized tomography (CT) scan that was largely unremarkable. The CT scan was to be followed by an esophagogastroduodenoscopy, but on the day before the procedure, the patient began vomiting large quantities of blood and experienced a cardiac arrest. He was transported to the hospital where he was resuscitated. He continued to bleed profusely, requiring exploratory laparotomy. At exploration, a large ulcer involving the first and second parts of the duodenum was identified and oversewn. A vagotomy and pyloroplasty with ligation of the gastroduodenal artery was also performed. Postoperatively, he did well until the 9th day when he again began vomiting large quantities of blood and became hypotensive. Following resuscitation, he continued to bleed and was quickly returned to the operating room where the bleeding ulcer was again oversewn and a hemigastrectomy was performed.

Postoperatively, his serum gastrin level was found to be elevated at 3000 pg/ml (normal, less than 150 pg/ml). The patient was started on omeprazole (60 mg per day). He was discharged home from the hospital after an uneventful period of recovery. For 18 months, serial CT scans of the abdomen have been obtained, but no evidence of tumor has been found.

Patient 2. This patient was a 39-year-old man who had a 10-year history of dyspepsia, secondary to ZES with gastrin levels in the 2000 pg/ml range. He was treated with H_2 blockers and omeprazole, with good control of symptoms. Approximately 3 years prior to this admission, he had undergone an exploratory laparotomy, but no primary tumor or liver lesions were seen. He was followed closely and underwent a CT scan approximately 1 year after exploration, which revealed a 5-cm liver lesion that was thought to be a hemangioma. Approximately 1½ years later, a repeat CT scan demonstrated that the size of the mass had in-

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Fig 1 — CT scan of the abdomen that demonstrates large right hepatic lobe tumor. Because of the highly vascular appearance of the lesion, this was initially mistaken for a hemangioma.



Fig 2 — Hepatic arteriogram which demonstrates tumor blush located in the right hepatic lobe.

creased (Fig 1). A percutaneous liver biopsy disclosed an islet cell tumor. A hepatic arteriogram showed a right hepatic lobe tumor blush (Fig 2).

A right hepatic lobectomy was performed without complications, with margins free of tumor. The pancreas and porta hepatis were also carefully examined for the presence of tumor or lymph nodes, but none was found. At 6 weeks postoperatively, his serum gastrin level was normal.

Patient 3. A 45-year-old woman was seen in 1985 with a 5-year history of peptic ulcer disease. She was being managed with H_2 blockers and antacids, which reportedly resulted in ulcer healing and symptomatic relief. However, the ulcers recurred 9 to 12 months after cessation of therapy. In March of 1985, she was admitted to a local hospital with acute onset severe abdominal pain. An exploratory laparotomy showed a perforated duodenal ulcer for which a vagotomy and antrectomy was performed. Postoperatively, she developed recurrent abdominal pain requiring cholecystectomy. Following this, recurrent severe abdominal pain prompted an upper gastrointestinal series that demonstrated the presence of two marginal ulcers located at the site of the Billroth II anastomosis (Fig 3). Fasting and stimulated gastrin levels were obtained, which were elevated at 625 and 1000 pg/ml, respectively. A CT scan was also performed in an attempt to identify a tumor, but only postoperative changes were noted. Following a course of H_2-blocker and antacid therapy, which failed to result in ulcer healing, a total gastrectomy was performed. Pancreatic exploration disclosed no evidence of a gastrinoma. She is seen regularly in follow-up and her symptoms are well controlled. Her weight has been well maintained despite her total gastrectomy, and there is no evidence of malignancy after 8 years.

Discussion

The introduction of H_2 blocker therapy in 1977 considerably reduced the mortality and morbidity associated with the ZES and led many physicians to refer fewer patients for gastric resection. Recent information, however, has indicated that H_2 blockers are not as effective as initial studies suggested.[3] Furthermore, the ZE patient frequently presents with a small tumor, often in an extrapancreatic location, and these can be identified in over 90% of the cases.

Diagnosis. The diagnosis of ZES usually has as its hallmark signs and symptoms of a severe



Fig 3 — Upper gastrointestinal barium radiograph that demonstrates ulcerations located at the site of the previous anastomosis.

ulcer diathesis. However, recent experience suggests that the spectrum of clinical manifestations has changed appreciably since the introduction of the gastrin assay in 1970. In 1987 Ellison et al[4] reported that prior to the availability of the gastrin assay, 80% of ZE patients presented with a serious ulcer complication. Also, more than two-thirds of these patients had undergone at least one operation for presumed ordinary peptic ulcer disease before a diagnosis of gastrinoma was made. Following the introduction of the gastrin assay, only 20% of patients presented with a serious ulcer complication and only one-third had undergone a previous ulcer operation.

The diagnosis of ZES is made after taking the history of the patient, which features intractable peptic ulcer disease, a fasting hypergastrinemia of greater than 200 pg/ml, gastric acid hypersecretion (basal acid output greater than 15 mEq per hour with an intact stomach or greater than 5 mEq per hour after a previous acid reducing operation), and a positive response to the secretin stimulation test (ie, an absolute increase of serum gastrin greater than 200 pg/ml).

The differential diagnosis for patients with gastric hyperchlorhydria with hypergastrinemia includes (in addition to gastrinoma) primary antral G cell hyperplasia, and in patients who have previously undergone a Billroth II gastrectomy, retained antrum in the duodenal stump. Retained antrum results in hypergastrinemia because the antral mucosal G cells are excluded from the acid stream, and the normal inhibitory mechanism of a low pH on gastrin release is circumvented. These patients, like those with gastrinomas, develop recurrent ulcers soon after a presumed adequate procedure. These patients can be identified by a secretin provocation test. Retained gastric antrum does not result in gastrin release in response to secretin.

Patients with antral G cell hyperplasia are differentiated from those with gastrinomas by an exaggerated gastrin response to meals, without an increase in gastrin secretion following secretin provocation. For patients with G cell hyperplasia, antrectomy is curative.

Following diagnosis of ZES, a thorough evaluation to detect gastrinomas should be performed. Currently available radiographic imaging techniques have achieved better preoperative localization of gastrinomas than in the past. Abdominal ultrasound can detect gastrinomas or hepatic metastases in 14% to 28% of affected patients. Using bolus contrast techniques, CT scans can detect 40% to 50% of gastrinomas and is especially useful for detecting hepatic involvement (72% sensitivity, 98% specificity). Recently Maton et al[5] reported excellent results using visceral arteriography to localize extrahepatic and hepatic gastrinomas. Percutaneous transhepatic portal venous sampling can successfully localize gastrinomas in up to 90% of the cases.[6]

Medical Management. Adequate control of acid hypersecretion, diarrhea, and ulcer symptoms can usually be achieved with cimetidine, ranitidine, famotidine, or omeprazole. Criteria established to assess adequacy of medical therapy include reduction of gastric acid output to more than 10 mM per hour in patients with intact stomachs and more than 5 mM per hour in patients with previous acid reducing procedure. Endoscopy is recommended every 6 to 12 months to ensure healing of ulcers, even if the patient is asymptomatic.

Many ZE patients require large doses of medication to maintain control over their disease, and frequently dosage increases are required. Failure rates can reach 40% to 50% with H_2 blockers,

compared with 2% to 3% with omeprazole. Omeprazole, which acts by inhibiting the H-K-ATPase pump, has become the drug of choice for most patients with ZES because of its superior potency, long duration of action (more than 48 hours), and its effectiveness at a constant dose over a prolonged period of time. Bonfils and Mignon[7] reported adequate, stable control of ulcer symptoms in 90% of the patients on omeprazole. Eight percent required an increased dose, while only 2% experienced side effects. The development of gastric argyrophilic carcinoid tumors has been reported in patients undergoing long-term treatment, which correlates with the development of an increased number of fundic enterochromaffin-like endocrine cells. Although the prevalence and significance of this finding is not known, these patients should be followed closely and have endoscopic examination at frequent intervals.

A number of studies have demonstrated the efficacy of the somatostatin analog SMS 201-995 in reducing serum gastrin and acid following subcutaneous injection.[8] Its efficacy is related to a reduction of ectopic gastrin secretion and a decrease in target organ response, leading to more stable inhibition of acid secretion, reduction in the parietal cell mass, and possibly an antigastrinoma effect.

The greatest advantage of effective antisecretory drugs has been to allow for elective pancreatic surgery to be performed under optimal conditions. Prior to the use of H_2 blockers, only 24% of ZE patients underwent pancreatic surgery only, whereas 75% did after 1975.

Surgical Management. The ideal treatment of patients with ZES is resection of the gastrinoma for cure. Surgical cure is defined as resection of all tumor so that the serum gastrin level becomes normal, the secretin stimulation test becomes negative, the patient requires no antisecretory medications, and the patient has no recurrent tumor on long-term follow-up. Two decades ago, surgical cure rates for gastrinoma were only 2% to 5%, but recently, several factors have been responsible for the dramatically improved surgical cure rate. These include improved patient selection, better knowledge of tumor location, and greater understanding of the natural history of the gastrinoma.

Operative treatment usually involves resection of a gastrinoma located in the pancreas, which is greatly facilitated by preoperative localization. When preoperative localization has been unsuccessful, abdominal exploration is recommended following a course of medical therapy. Ninety percent of tumors are found in an area bounded by the cystic duct, the body of the pancreas, and the inferior portion of the head of the pancreas. This area has been termed the gastrinoma triangle (Fig 4). During exploration, attention is directed to the region of the cystic duct and porta hepatis, with all lymph nodes found removed and submitted for frozen section. The lesser sac, pancreas, and retroperitoneum along the inferior border of the pancreas are also completely explored to detect any lesions.

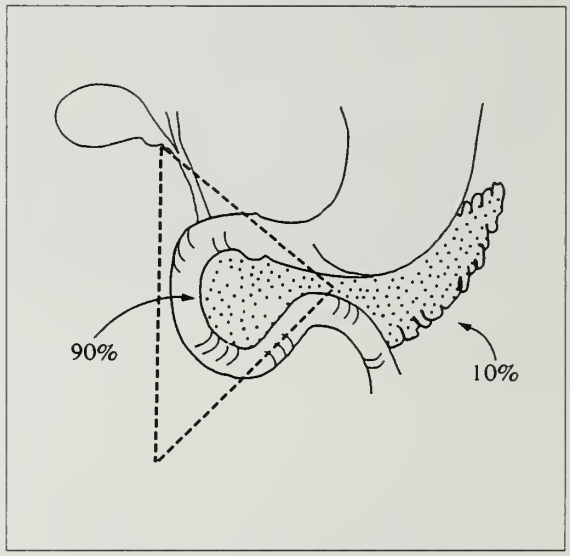


Fig 4 — Schematic diagram of boundaries of the gastrinoma triangle.

The use of intraoperative ultrasound to identify gastrinomas has been proposed. Norton et al[9] reported this modality was equal to palpation in localizing gastrinomas and occasionally is able to detect tumors that are not palpable. Therefore, intraoperative ultrasound should be considered an additional tool in the armamentarium of the surgeon.

Many patients — up to 40% of some series — have occult gastrinomas that elude detection.[10, 11] Of these, the great majority are located in the duodenum and are less than 2 mm in size. Because of the small size of these tumors, which are rarely palpable, a duodenotomy is made in the second portion of the duodenum, and the mucosa is everted and meticulously examined. Despite the small size, Thompson et al[12] reported

identifying 45 of 46 occult gastrinoma using preoperative selective venous sampling and duodenotomy.

Gastrinomas frequently metastasize to regional lymph nodes in the region of the porta hepatis. Freisen[13] reported that gastrinomas located in regional lymph nodes frequently are metastatic from primary duodenal gastrinomas. In patients with metastatic lymph node involvement without hepatic involvement, excision of the diseased lymph nodes resulted in normalization of the serum gastrin level. In patients with nodal gastrinomas without an identifiable primary, excision of diseased nodes resulted in normal serum gastrin levels in 75% of patients. Thus, metastatic lymph node involvement should not deter one from providing aggressive surgical treatment.

Patients with hepatic or widespread metastatic involvement represent the subgroup with the poorest prognosis. Ellison and Wilson[14] reported a 20%, 5-year survival in patients with unresectable disease. In 1986 Norton et al[15] reported extensive debulking and hepatic resection in four patients with widespread disease, which resulted in biochemical cure in two patients, reduction of antisecretory medication, and improved quality of life after a median follow-up of 24 months.

In patients with unresectable metastatic disease, various chemotherapeutic regimens have been tried. These agents have been uniformly unsuccessful in inducing remissions, and because of the side effects of the drugs, modalities such as long-acting somatostatin or interferon are being used experimentally.[15]

Conclusion

Patients with ZES secondary to gastrinoma present a formidable diagnostic and surgical challenge. The diagnosis should be considered in all patients with atypical or recurrent ulcer disease. Because of the significantly improved survival of patients undergoing complete resection, an exhaustive search should be made to identify the gastrinoma, after which exploratory laparotomy with excision of the tumor is performed.

In patients in which preoperative localization is unsuccessful, exploratory laparotomy with duodenotomy is indicated to identify occult duodenal wall gastrinomas. Furthermore, resection of all metastatic lesion, if possible, appears to result in improved long-term survival.

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Assistance for Flood Areas

TO THE EDITOR: The state of Iowa is currently suffering through a devastating natural disaster in the form of record flooding. The flood waters have begun to recede somewhat and the cleanup has begun in earnest. Tap water has now been restored to Des Moines, though it will not be drinkable for at least another week.

Though it is too early to assess the damage caused by the floods of 1993, it is certain the cost will be very high. One-third of Iowa's corn and bean crops are gone and hundreds of people have lost everything, including their homes. Business losses just in the city of Des Moines could exceed $700 million. Damage to bridges, roads, sewer systems, etc, in many Iowa cities and towns has yet to be assessed but is sure to be extensive.

Fortunately, Iowa hospitals and clinics were able to continue functioning on a normal basis. There has been no outbreak of disease and the death toll has been fairly low considering the magnitude of this calamity. As a preventive measure, volunteers have given tetanus shots to thousands of Iowans in recent days.

The expressions of concern and offers of assistance which I and members of the IMS staff have received from medical societies across the country have been heartwarming. The support and assistance offered by generous Americans in every state has made this tragedy more bearable for many Iowans. Many of you have asked what you might do to help.

Financial donations are sorely needed to assist Iowans forced out of their homes so quickly they were able to save nothing. Following are the addresses of several organizations accepting donations:

Iowa Cares
666 Walnut
Des Moines, Iowa 50309

American Red Cross
2116 Grand Avenue
Des Moines, Iowa 50312
ATTN: Brother Phillip

Salvation Army
1330 6th Avenue
Des Moines, Iowa 50304
ATTN: Lt. Hellstrom

You may wish to publicize these addresses in your newsletters, magazines or other member communications, in case some of your members wish to make donations.

Again, thank you for your expressions of concern. Pray with us that the heavy rains have ended and that we will come through with no further harm to people and property.

John Anderson, MD
President
Iowa Medical Society

Fetal Sex Prediction: The Heart of the Matter

TO THE EDITOR: *There are many old wives' tales concerning prenatal diagnosis of fetal sex. These range from and are not limited to the following: (1) how a woman carries her baby (high equals girl); (2) first morning urine plus Drano (blue yellow coloration equals boy); (3) the Romanian salt test (put salt in mom's hair and if she scratches her nose its a boy); (4) an uptight father equals a girl; and (5) if a mom's leg hair grows faster a boy is on the way. Perhaps the most popular held view is that fetal heart rate may be an indication of fetal sex. The old wives' tale suggests that a slower rate may equal a boy. To our knowledge only one paper in the literature addresses this issue*[1] *and it found no differences in fetal heart rate based upon fetal sex. The purpose of this study was to test the hypothesis that fetal sex can be determined prenatally simply by ascertaining the fetal heart rate.*

Study Design

One hundred twenty-eight women agreed to participate in this prospective study performed at the University of Kentucky Medical Center. At each prenatal visit the patients of the senior investigator (SMC) had the fetal heart rate auscultated for one minute. This number was recorded on the prenatal record. At 32 weeks gestation the fetal sex was predicted based on the average of previous recorded values. A male sex was assigned if the average fetal heart rate was less than 140 bpm. Conversely, a female sex was predicted if the rate equalled or exceeded 140 bpm. Importantly, if ultrasound or prenatal diagnostic testing was performed and sex noted, this information was not revealed to the senior investigator. At the time of

delivery the infant's sex was recorded and the predicted versus actual sex compared.

Results

To date, 100 study participants have delivered. The findings of this investigation are summarized in the table below.

	Actual Female	Actual Male
Predicted female	42	15
Predicted male	4	39

The positive predictive value for a male is 91% and for a female is 74%.

Conclusions

From the results of this study, we conclude that there is a positive correlation with fetal heart rate and sex prediction. There appears to be some truth to the old wives' tale; however, the mechanism causing such differences is not known.

Steve Hall, MD
Kyle King, MD
Susan M. Cox, MD
University of Kentucky Medical Center
800 Rose Street
Lexington, KY 40536

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"Push the Envelope"

TO THE EDITOR: I read Dr Martha K. Heyburn's article in the *Journal of the Kentucky Medical Association,* Vol 91, No. 6-243.

I agree with Ms Heyburn's horror of rationing. Rationing, at best, implies the ideal of an equal distribution of limited resources among equal recipients. Physicians, however, know that medical care is not a commodity like potatoes that can be divided into equal lots nor are patients equal with respect to their ability to respond and benefit from treatment; further, why should there be any inherent limitation to what is mainly an intellectual resource? Can a bureaucrat answer these questions?

Admittedly, the public is very tired of the ever escalating cost of specialty medical services. Part of the problem is that we have just not used our common sense: I would ask Dr Heyburn what is Coby Howard's chance of responding to the bone marrow transplant? How much more money will be spent if he does respond? Will he ever work?

There is a resolution to this contradiction: Specialty medical services can be provided more efficiently by transferring some of this care to the generalist.

Having worked in rural hospitals most of my career, I am aware that people in the academic centers have vastly differing views of what generalists who work in such hospitals are qualified to do. However, in order to "expand the envelope" the generalist of the future should do more of this than the generalist of today. Specialty groups must transform themselves from an exclusive role to an inclusive role. Organized medicine must set as a goal the ideal that all commonly performed medical procedures of proven effectiveness should be performed in a community hospital. This goal should not be a static one but should be ever changing. The specialty societies must teach the general practitioner and general specialist working in a small hospital to provide these services. Only through competition and common availability will these services be affordable: The system can be more efficient and can provide less expensive specialty services.

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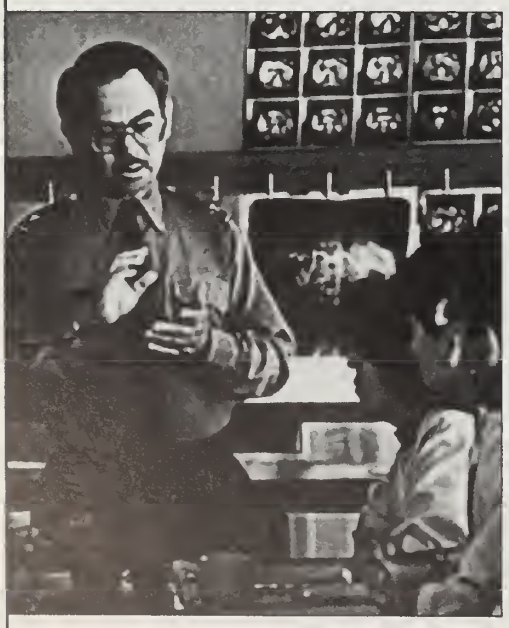
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A Lion in a Den of Daniels

"There is something wrong with a system that is going bankrupt from medical care on one hand and on the other hand won't allow a natural death to occur without offering artificial support."

I may not be a medical lion but neither am I a harbinger of death. I try very hard for a favorable outcome in the event of an acutely ill patient who even has a slim chance of a return to a decent quality of life. I call in, early-on, consultants and sub-specialists to assist in their areas of expertise.

But there comes a time in an elderly patient who turns acutely ill or the acutely ill patient who begins the "medical cascade" of multi-system failure, when the physician must step back, slowly close the bag, and offer only relief of suffering but no support systems.

What was it called in the "old days"? Skillful neglect? What is it called in the current days? Withholding therapy!

Fine! Good! We all agree. So long as the "all" are the patients and their living will, the patient's family, and all physicians who are on board. Frequently however we have a problem and a dissenting view.

The problem comes from the nursing homes in general and the floor nurse or charge nurse in specific. "They" want something done. It matters not if the patient is a "no code" status. Nurses do not want anyone to expire during their watch. If a problem arises . . . call a private ambulance service or the EMS and transport the patient to an emergency room and let the attending physician know what you have done.

If a terminal patient is dehydrated then transfer them to a skilled nursing area where they can receive intravenous fluids. If no veins are available then put down a nasogastric feeding tube for sustenance. If a feeding tube won't pass, then a gastrostomy tube will do for daily caloric needs and fluid intake.

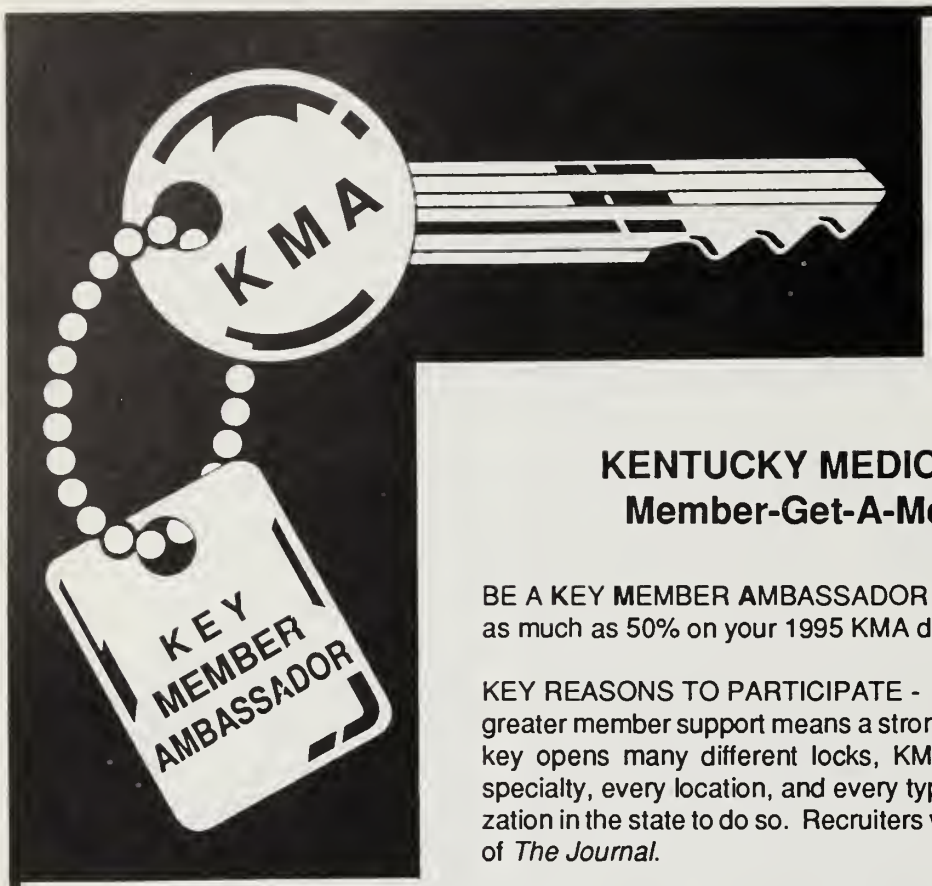
Now don't let me mislead you. All of the above are done according to doctor's orders. But the coercion comes from the nursing home rules that no patient may go longer than 3 days with no food or hydration, and then parenteral or intravenous support must be started.

In the natural history of death, the sequence is dehydration to confusion to stupor to coma to cessation of life. Artificial interruption of any of these stages can prolong life an indeterminate period.

Believe me. This is not an indictment of nursing homes and their staff. They have served me and my patients well over the years. I am confident that they too have to operate under federal and state guidelines to avoid patient abuse charges and need relicensure each year.

There is something wrong with a system that is going bankrupt from medical care on one hand and on the other hand won't allow a natural death to occur without offering artificial support. I would plead for a change in direction.

Milton F. Miller, MD



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"Kentucky's Youth at Risk"



Gloria J. Griffin

The available statistics are overwhelming. You might think that our youth have a death wish, or has it just become easier for parents to choose not to become involved in what is happening in their own communities. The basis of our organization has always been concern for the health and welfare of the citizens of our community. Who better to involve in addressing this critical problem than physician spouses.

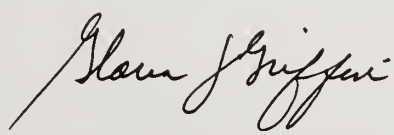
Young adults and adolescents experience frustrations and hopelessness as a result of unresponsiveness to their emerging and continual emotional challenges. As a result of fractured or non-existent family structure, many youth have no positive role model to emulate. This often fosters unrest, insecurity, anger, fear, and frequently, violent behavior.

- Many of these children seek approval and love through premature and irresponsible sexual activity, and not infrequently either an unintended pregnancy or a planned pregnancy, with the unrealistic hope that this will provide a new sense of worth for the teen parent.
- Frequency of sexually transmitted diseases is rising at alarming rates among teens. In certain areas, transmission of HIV and resultant AIDS threatens an entire generation.
- Do children seem to be more violent these days? The evidence is clear that violence in general is increasing over recent decades, and some studies indicate that the increase has been even greater among children. Media violence affects our young more than adults because they often cannot distinguish between fantasy and reality.
- A recent survey of 2,508 children, conducted by LH Research Inc in 96 middle and high schools nationwide, concluded that 60% of the students could quickly get a hand gun; 39% said they have known someone who was killed or wounded by gunfire. I'm sure you think this is just a fact in the inner cities, but in fact the availability of weapons seems to be similar among students in suburbs, small towns, and rural areas as well.

In order to be effective as community leaders, physician spouses must acknowledge and then educate themselves about these problems. Then we must engage in developing strategies to protect Kentucky's future.

If you care about the youth of our communities as I believe we all do, and if you accept the community leadership role which is part of being a spouse of a physician, I hope to see you at the KMAA "Youth at Risk" Fall Conference on September 28, 1993, at the Hyatt Regency, Conference Theatre, in Louisville.

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TURN PAGE FOR FALL BOARD AGENDA

KMA ALLIANCE Fall Board and Conference Meeting

September 27-29, 1993

The KMAA meetings will be held in conjunction with the KMA Annual Meeting at the Hyatt Regency in Louisville.

Monday, September 27

8:00 KMA Alliance committee meetings
9:00 AMA/ERF check presentation at the KMA House of Delegates by Beryl Dodds, Immediate Past President of AKMA
1:00 KMA Alliance Board of Directors meeting

Tuesday, September 28

9:00-12:30 KMAA Conferences — "Kentucky's Youth at Risk"
10:00-6:00 McFund Boutique, Pimlico B&C
12:30 Luncheon in the Regency Ballroom South B

Wednesday, September 29

9:00 Randolph D. Smoak, Jr, MD, Chicago, IL
"An Overview of Family Violence"
10:00-6:00 McFund Boutique, Pimlico B&C

On Tuesday and Wednesday the KMAA will sponsor a "MCFUND" Boutique. The proceeds from the sales during these two days will benefit the Ronald McDonald Houses in Lexington and Louisville, and the Ephraim McDowell House in Danville. The meetings and boutique are open to all physician spouses. If you are not a member, perhaps you might find these meetings informative and choose to join us to help impact the future of Kentucky's youth.

Information on registration and luncheon reservations may be obtained from Carol Goodin, 3012 Lightheart Rd, Louisville, KY 40222.

Results of the Maternal and Child Health Committee Survey of Family Practitioners and Obstetrics and Gynecology Specialists

The KMA Committee on Maternal and Child Health completed a survey of 1,100 family physicians and OB/GYNs in August 1992. The survey was a followup to a similar survey conducted by the Committee in 1987. The response rate was 40%. The University of Kentucky Research Center analyzed the results of the survey and produced the written summary.

The primary policy issue in conducting this survey was as follows:

1. *To gather information on the availability of obstetrical services in Kentucky, particularly in rural areas.*
2. *To determine the reason physicians cease obstetrical practice.*
3. *To determine effects the cost and availability of professional liability insurance and the tort system have on the availability of obstetrical services.*
4. *To provide results of this information to the two Kentucky medical schools for use in increasing the number of obstetricians in Kentucky and to encourage family physicians to provide obstetrical services.*

While these were the major purposes of the survey, there were several other questions which sought opinions of physicians. Those questions included whether or not they were comfortable working with mid-level practitioners and the general relationship between obstetricians and family practitioners. The survey will hopefully be utilized by medical schools, scholarship programs, and state government to encourage placement of obstetricians in areas where obstetrical care is lacking.

J. Gregory Cooper, MD, Chairman
Committee on Maternal and Child Health

Prepared for The Kentucky Medical Association by James G. Wolf, University of Kentucky Survey Research Center.

In August of 1992 the Kentucky Medical Association Committee on Maternal and Child Health conducted a survey of all family physicians and obstetrics and gynecology specialists in the state of Kentucky. The committee sent out 1,100 questionnaires and received responses from 440 physicians. Although a 40% response rate is less than optimal, it is considered adequate for estimating prevalence and attitudes throughout the state. The questions focused on current obstetrics practices, relationships with other health care professionals in providing obstetrics care, legal and insurance issues, and general issues regarding obstetrics in their communities. The completed questionnaires were coded and the data were entered by the University of Kentucky Survey Research Center. This report is a summary of those results.

This report is divided into three sections: current and potential availability, relationships with other health care professionals, and other obstetrics related issues. The results presented in the body of this report are broken out, where appropriate, by whether or not the respondent was a family practitioner or an OB/GYN specialist. The complete text and results of the survey appear in the appendix.

Current and Potential Availability

Table 1 shows the breakdown of physicians currently practicing obstetrics in Kentucky by type of specialty. While fewer than one in 10 family

Table 1. Physicians Practicing Obstetrics by Obstetrics Practice Status (N = 440)

	Total	Currently Practicing Obstetrics
Family Practice	68.6%	8.7%
Obstetrics/Gynecology	31.4	82.5
Combined	100.0	31.9

Table 2. Key Issues Related to Resuming or Continuing in OB by Obstetrics Practice Status

What would enable you or persuade you to continue to practice obstetrics?
(MULTIPLE ANSWERS ALLOWED)

	Total	Currently Practicing OB Yes	No
Nothing	52.7	5.9	74.4
Liability insurance reform	31.2	55.1	20.0
Hiring more associates	7.6	12.7	5.2
I plan to continue/resume OB	5.7	17.8	0.0
Adequate payment	4.9	10.2	2.4
Less gov't & insurance co. intrusion	3.5	8.4	1.2
Support facilities	3.3	5.9	2.0
Retraining; mini-residency for refresher	1.9	0.0	2.8
Patients	1.6	4.2	0.4
Better relationship with OB/GYNs	1.4	2.5	0.8
Other issues	1.1	3.3	0.0
Total respondents:	368	118	250

Table 3. Relationship Between Types of Practices by Obstetrics Practice Status

If you ore o family proctice physicion, whot is your relotionship with obstetrics in your community?
(MULTIPLE ANSWERS ALLOWED)

	Total	Currently Practicing OB Yes	No
Good relationship	39.9	57.7	38.1
Referrals	26.5	19.2	27.2
None or no other obstetricians in area	16.2	15.4	16.3
Newborn care	9.5	0.0	10.5
Poor relationship	4.6	0.0	5.0
Consultation	4.2	3.8	4.3
See pregnant patients for other problems	3.9	0.0	4.3
Stopped OB practice	2.5	0.0	2.7
Assist c-section	1.8	0.0	2.0
Family practitioner — do OB	0.4	3.9	0.0
Total Respondents	283	26	257

NOTE: This question was only asked of Family Practitioners.

If you ore on obstetricion, whot is your relotionship with fomily proctice physicions in your community?
(MULTIPLE ANSWERS ALLOWED)

	Total	Currently Practicing OB Yes	No
Good relationship	58.5	58.7	57.1
Referrals	17.9	19.3	7.1
None or no FPs practicing OB in area	14.6	12.8	28.6
Consultation	6.5	7.3	0.0
Poor relationship	3.3	2.7	7.1
Competition	2.4	2.7	0.0
Other issues	1.6	1.8	0.0
Total Respondents	123	109	14

NOTE: This question was only asked of OB/GYN Specialists.

practitioners are practicing OB (8.7%), over one in six OB/GYN specialists (17.5%) are *not* practicing OB. This result suggests that, of the 1,100 family practitioners and OB/GYN specialists in the state, only about 350 are currently practicing OB.

When asked to describe issues that would facilitate their involvement in resuming or continuing an OB practice (Table 2), a majority responded that nothing would encourage them to do so. Fewer than 6% of currently practicing OB physicians gave this response, but almost three-fourths of those not practicing OB stated that nothing would persuade them to begin this type of practice. Of those who did offer some suggestions, the reform of the existing liability insurance regulations was far and away the most frequently indicated issue reported. Other issues raised of much less importance were the hiring of more associates and more adequate payment for services provided.

Relationship with Other Health Care Providers

Family practice physicians and OB/GYN specialists were each asked to characterize their working relationship with the other in their respective communities. Table 3 shows the outcome of the results for the two separate types of practices. The most common response for both groups was the subjective assessment that relationships with the other type of practice was good. Obstetricians were much more likely to characterize their relationship with family practitioners as good (58.5%) rather than the reverse (39.9%). The other types of responses were more oriented toward description of specific types of activities in which the two groups were engaged (if at all) and included referrals, no relationship (often due to the fact that there were no physicians active in the other specialty in that community), and other issues like newborn care or other general types of consultation. Fewer than 5% in each group characterized their relationship with the other specialty as poor.

The questionnaire included other more general questions about sharing the care of patients with other types of health care providers. Respondents were asked about their willingness to become involved in situations where a pregnant woman would receive prenatal care up until a predetermined gestational age and then be referred to another regional center for continued prenatal care and/or delivery. A follow up ques-

tion asked if the physician would be willing to accept a referral under this situation. Another question asked if the physician would be willing to work with a midwife or nurse practitioner. The results of these questions appear in Table 4.

Only about one-third of both categories of respondents indicated that they would be willing to only provide partial prenatal care to a pregnant woman with the plan to transfer her to another facility for completion of that care and delivery of the child. Significant differences between OB practitioners and the others emerged when asked if they would be willing to accept transfers under this type of arrangement. Almost half (48.9%) of those practicing OB indicated they would compared to the 29.9% of those not practicing OB. A full two-thirds of those respondents practicing OB stated they would be willing to work with a midwife or nurse practitioner compared to only one-fourth of those not practicing OB.

Table 4. Willingness to Wark With Other Praviders by Obstetrics Practice Status

	Total	Currently Practicing OB Yes	No
Willing ta pravide partial prenatal care then transfer patient	33.3	31.6	34.0
(N)	(418)	(133)	(285)
Willing to accept referred patient far remaining prenatal care and delivery	36.5	48.9	29.9
(N)	(389)	(135)	(254)
Willing ta wark with midwife or nurse practitianer	38.4	66.9	24.5
(N)	(388)	(127)	(261)

Table 5. Majar Barriers to Improving Cammunity Obstetrics Care by Obstetrics Practice Status?

What da yau feel are the majar problems with impraving abstetrical care in yaur cammunity?

(MULTIPLE ANSWERS ALLOWED)

	Total	Currently Practicing OB Yes	Na
Lack af specialist in the cammunity	25.8	18.6	29.7
Liability cancern	21.1	15.0	24.4
Patient attitude and knowledge	14.9	23.0	10.5
Providing care ta all, esp prenatal care	10.2	15.9	7.2
No problem, present care is excellent	9.6	9.7	9.6
Don't know; nothing	9.0	2.7	12.4
Paar reimbursement	8.4	13.3	5.7
Lack af facilities	8.1	8.9	7.7
Uninsured & Medicaid	4.0	6.2	2.9
Gavernment & insurance intrusion	3.4	4.4	2.9
Nat many accept Medicaid	3.4	5.3	2.4
Unavailability af birth cantral	2.5	4.4	1.4
Attitude af nurses and/ar dactars	1.9	0.9	2.4
C-sectians	0.9	0.9	1.0
Reduce casts ta patients	0.9	0.9	1.0
Campetitian	0.9	0.9	1.0

Other Obstetric Related Issues

There were two final questions in the questionnaire that dealt with maintaining an obstetrics practice. Respondents were asked if they had ever had an obstetrical related lawsuit. Twenty-three percent of all respondents said they had at one point in their career. Of those who were currently practicing OB, 44.2% had such a lawsuit as compared to 12.3% of those who were no longer practicing OB.

The final questions asked the respondent to indicate what they felt were the major problems with improving obstetrical care in their community (Table 5). Although the most common issue raised by respondents overall was the need to have more specialists in their community (the issue raised by 29.7% of respondents not practicing OB), the problem cited most often by physicians practicing OB was the need to improve the knowledge and attitudes of their patient population regarding maternal health and prenatal care. Other issues raised centered on concerns about insurance and legal liability and the need to expand access to prenatal care. Fewer than 10% of both groups of physicians felt their community provided such appropriate care that there was no need for improvement.

Conclusions

A seriously low proportion of physicians are practicing obstetrics in Kentucky among those who are qualified to do so. Less than one-third of the family practitioners and OB/GYN specialists in the state report that they are currently practicing obstetrics. Nearly three-fourths of those who could but are not practicing OB, perhaps as many as 500 physicians in the state, have no apparent intention of resuming their OB practice. Among those who are or might be practicing OB, reform of the current liability regulations is the single most important thing cited that might enable or persuade these doctors to resume or continue their OB practice.

APPENDIX

KMA Survey Results

Q1. *What is your specialty?*

	Frequency	Percent
Family Practitioner	299	68.6
OB/GYN	137	31.4

Frequency Missing = 4

Q2. *Are you currently practicing obstetrics?*

	Frequency	Percent
Yes	140	31.8
No	300	68.2

Q3: *What would enable you or persuade you to continue to practice obstetrics?*

368 Answered, 72 skipped

194	52.7	Nothing
115	31.2	Liability insurance reform
28	7.6	Hiring more associates
21	5.7	I plan to continue
18	4.9	Adequate payment
13	3.5	Less government & insurance company intrusion
12	3.3	Support facilities
7	1.9	Retraining; mini-residency for refresher
6	1.6	Patients
5	1.4	Better relationship with OB/GYNs
4	1.1	Other issues

Q4: *If you are a family practice physician, what is your relationship with obstetrics in your community?*

283 Answered, 157 skipped

113	39.9	Good Relationship
75	26.5	Referrals
27	9.5	Newborn care
27	9.5	Don't do, nothing
19	6.7	No other obstetricians
13	4.6	Poor relationship
12	4.2	Consultation
11	3.9	See pregnant patients for other health problems
7	2.5	Stopped OB practice
5	1.8	Assist c-section
1	0.4	Family practitioner — do OB

Q5: *If you are an obstetrician, what is your relationship with family practice physicians in your community?*

123 Answered, 317 skipped

72	58.5	Good relationship
22	17.9	Referrals
9	7.3	No FP's practicing OB in area
9	7.3	None
8	6.5	Consultation
4	3.3	Poor relationship
3	2.4	Competition
2	1.6	Other issues

Q6: Would you be willing to provide prenatal care up to a defined gestational age then refer the patient to a regional facility for continued prenatal care or for delivery?

	Frequency	Percent
Yes	139	33.3
No	279	66.7

Frequency Missing = 22

Q7. *Would you be willing to accept referrals under the conditions described in question 6:*

	Frequency	Percent
Yes	142	36.5
No	241	62.0
Other	6	1.5

Frequency Missing = 51

Q8. *Would you be willing to work with a nurse practitioner or a certified midwife?*

	Frequency	Percent
Yes	149	38.4
No	239	61.6

Frequency Missing = 52

Q9. *Have you ever had an obstetrical related lawsuit?*

	Frequency	Percent
Yes	90	22.7
No	307	77.3

Frequency Missing = 43

Q10. *What do you feel are the major problems with improving obstetrical care in your community?*

322 Answered, 118 skipped

83	25.8	Lack of specialist in the community
68	21.1	Liability concern
48	14.9	Patient attitude and knowledge
33	10.2	Providing care to all, prenatal care
31	9.6	No problem, present care is excellent
29	9.0	Don't know; nothing
27	8.4	Poor reimbursement
26	8.1	Lack of facilities
13	4.0	Uninsured & medicaid
11	3.4	Government & insurance intrusion
11	3.4	Not many accept medicaid
8	2.5	Unavailability of birth control
6	1.9	Attitude of nurses and/or doctors
3	0.9	C-sections
3	0.9	Reduce costs to patients
3	0.9	Competition

KMA Releases Domestic/Interpersonal Violence Educational Packet



Baretta Casey, MD

The Kentucky Medical Association has developed an educational packet on domestic/interpersonal violence for all active Kentucky physicians and residents. The educational packet includes brochures on child abuse and adult/elderly abuse, a patient brochure on domestic violence, a state map with spouse abuse centers in the state, a poster on domestic violence, and an order form for additional copies of the patient brochure. The packets will be distributed before the KMA Annual Meeting.

Domestic violence cuts across all racial, ethnic, religious, educational, and socioeconomic lines and is characterized as a pattern of coercive behavior that may include repeated battering and injury, psychological abuse, sexual assault, progressive social isolation, deprivation, and intimidation. Conservative studies indicate that two million women per year are assaulted by their partners, but experts believe that the true incidence of partner violence is probably closer to four million cases per year. The problems of child abuse present additional concerns for the medical community. The causes of child abuse and neglect are complex and varied. Child maltreatment can be inflicted by anyone responsible for caring for children, and it occurs in all types of families and settings. Children of all ages can be physically abused. Although infants and young children are more likely to receive serious or life-threatening injuries, adolescent abuse also occurs and often is unrecognized.

The educational packet was developed by the "Blue Ribbon" Subcommittee on Domestic/Interpersonal Violence. In early 1992, the Community and Rural Health Committee recognized the growing need for the medical community to address the problem of domestic violence in our state. The Community and Rural Health Committee, under the direction of Chairperson Ardis D. Hoven, MD, empowered me to chair the newly appointed Subcommittee on Domestic/Interpersonal Violence. Recognizing that stemming the problem of domestic violence extends beyond physicians simply treating patients' injuries from abuse, the Subcommittee appointed a broad mix of representation to establish goals to address domestic violence as a community issue rather than only a medical one. Attorney General Chris Gorman; Jefferson County Attorney Mike Conliffe; and Fayette Commonwealth Attorney Ray Larson were appointed to the Subcommittee as well as representatives from the Kentucky Domestic Violence Association; the Department of Social Services, Family Services Program, Adult Protective Service; and the Center for Women and Families.

The Subcommittee, through extensive discussion, developed short-

"Recognizing that stemming the problem of domestic violence extends beyond physicians simply treating patients' injuries from abuse, the Subcommittee appointed a broad mix of representation to establish goals to address domestic violence as a community issue rather than only a medical one."

and long-range goals.

Short-term:

— Educate physicians on the problem of domestic violence.

— Instruct physicians on the present laws in Kentucky as they relate to reporting known and suspected domestic violence.

— Educate communities by providing brochures to physician offices, hospitals, and other public places.

Long-term:

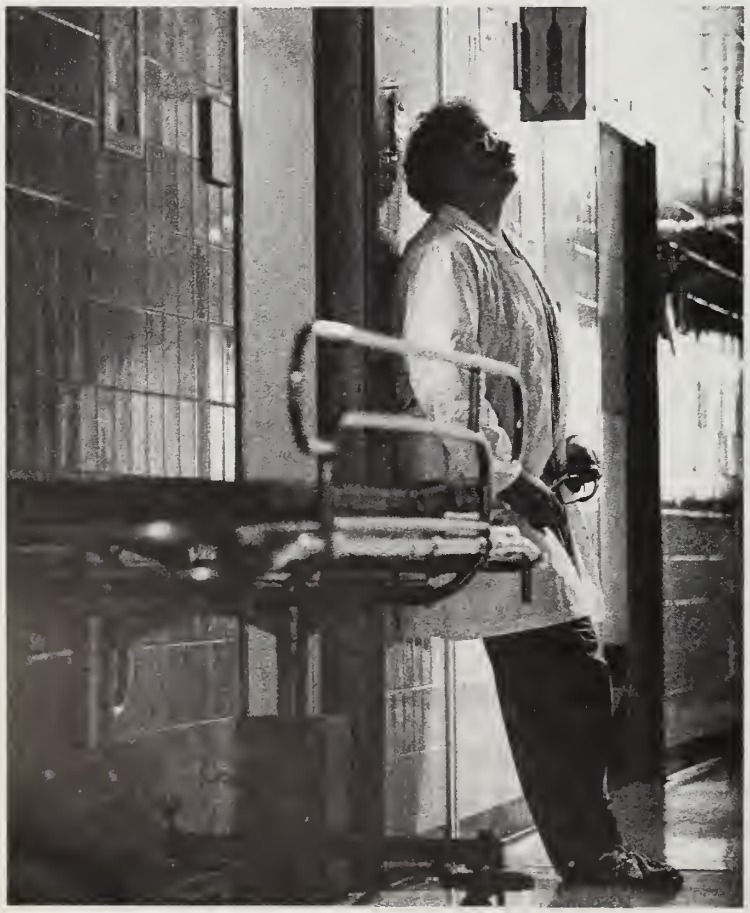
— Recommend that medical schools implement courses on diagnosing abused victims. The Committee noted that physicians' treatments and attitudes toward abused victims can make a significant impact upon whether a victim seeks further help and considers filing criminal charges.

"We recognize that the problem of domestic violence is not short-term and will not simply disappear. This is a long-term problem that will require everyone to lend a hand. With no easy answers, the problem must be addressed one step at a time."

The Subcommittee has provided extensive input into the development of the domestic violence educational packet. We recognize that the problem of domestic violence is not short-term and will not simply disappear. This is a long-term problem that will require everyone to lend a hand. With no easy answers, the problem must be addressed one step at a time.

We encourage you to utilize the information contained in the domestic violence packets so that the medical community in Kentucky can take a step in the right direction to help stem the violence.

Baretta Casey, MD
Chairperson
Subcommittee
Domestic/Interpersonal Violence



"Being a patient advocate is what being a physician is all about."

Dr. Kevin Fullin, Cardiologist, Kenosha, Wisconsin,
Member, American Medical Association

Why would a cardiologist get involved in the issue of family violence? Perhaps, because what he saw simply cried out for action.

"Fully a third of all women's injuries coming into our emergency rooms are no accident," says Dr. Fullin.

While others were content to downplay the issue of family violence, Dr. Fullin would not. He petitioned state officials, and through his efforts the first Domestic Violence Advocate Program in his state was created.

"Organized medicine must serve as an advocate for patients," stressed Dr. Fullin.

The American Medical Association (AMA) couldn't agree more. We're committed to focusing physician attention on the issue of family violence.

Become a member of the AMA today.

Members of the AMA are encouraged to join their state, county and specialty societies.

American Medical Association
Physicians dedicated to the health of America



David W. Carby Joins KMA Staff

David W. Carby has joined the KMA staff as Director of Governmental Relations and Staff Counsel. He is serving the Association in various capacities, is assisting in KMA's legislative activities, and is staffing several committees within the KMA structure.

A native of Louisville, Mr Carby earned a Bachelor of Science degree in Corrections from Eastern Kentucky University in 1978 and a Juris Doctor degree from the University of Louisville School of Law in 1981.

He comes to KMA after several years as General Counsel to the Kentucky Board of Medical Licensure.

PEOPLE

During the Annual Meeting of the American Medical Association held in Chicago, **Baretta Casey, MD,** who will begin her third year of family practice residency at Trover Clinic this year, was named by the AMA Board of Trustees to serve on the Advisory Committee on Women in Medicine. Dr Casey currently serves as the President of the KMA Resident Physicians Section and has been very active in KMA through both her student and resident years. She also serves on the KMA Committee on Community and Rural Health and chairs its Subcommittee on Domestic Violence.

Judy Linger, MD, a third-year psychiatry resident at UK was elected as an Alternate Delegate from the Resident Physicians Section to the AMA House. Dr Linger has also been quite active in KMA and is currently President-Elect of the KMA RPS.

Both physicians' terms will begin with the start of the new calendar year.

Beryl Dodds (Mrs C. R.), KMAA Immediate Past President, has been appointed to the AMAA AMA-ERF Committee.

Ronald E. Waldridge, MD, KMA 7th District Trustee, Shelbyville, recently became the 46th President of the Kentucky Academy of Family Physicians. Other members elected to the Board were **Robert L. Nold, Sr, MD,** Louisville, President-Elect; **Sandford Weiler, MD,** Harlan, Vice President; **Nancy C. Swikert, MD,** Florence, Secretary; **John H. Darnell, MD,** Ashland, a second term as Treasurer; **Larry S. Fields, MD,** outgoing President, was elected Alternate Delegate to the AAFP, and **Frank Garamy, MD,** Crescent Springs, was elected AAFP Delegate. District Directors elected were **Patricia Elliot, MD,** Mayfield; **Eric Norsworthy, MD,** Hartford; **James Sills, MD,** Hardinsburg; **James Smith, MD,** Shelbyville; **Marguerite Schabell, MD,** Ft. Mitchell; **John Patterson, MD,** Irvine; **Larry McClure, MD,** Ashland; and **Bruce Barton, MD,** Corbin. The Kentucky Academy is a chapter of the American Academy of Family Physicians (AAFP), the largest specialty group in the US with more than 70,000 members.

Maurice John, MD, a Jeffersonville, Indiana, ophthalmologist, has been elected to a 1-year term on the Board of Directors of the American Board of Eye Surgery.

W. Ben Kibler, MD, medical director of the Lexington Clinic Sports Medicine Center, was recently elected to the Board of Trustees of the American College of Sports Medicine. Dr Kibler will begin a 3-year term as one of six newly elected physicians on a national board comprised of 18 members.

Walter H. Zukof, MD, Louisville, has been named Citizen Doctor of the Year by the Kentucky Academy of Family Physicians.

UPDATES

UK Receives Grant to Focus on Women's Substance Abuse

The University of Kentucky Center on Drug and Alcohol Abuse has received a $300,000 grant to create a statewide focus on substance abuse among women. The funding was awarded by the Division of Substance Abuse, Cabinet for Human Resources, through the Bluegrass Mental Health Retardation Board. The UK program will be housed off campus at 146 Transcript Ave.

The new program will work with representatives of the UK Department of Psychiatry, Colleges of Nursing and Social Work, and the PRIDE (Perinatal Recovery Infant Development and Education) program, a joint project of the UK Chandler Medical Center and Bluegrass East Comprehensive Care. The Institute will serve as a resource, training, and technical assistance center for substance abuse and health, human service, and education professionals throughout the state.

Ultrasound Method Takes Some Guesswork Out of Coronary Surgery

A device being used by University of Louisville doctors may take some of the guesswork out of treating coronary problems, according to a report from the University.

Cardiologists **J. David Talley, III, MD,** and **Wayne M. Shugoll, MD,** are using a Doppler ultrasound system to measure blood flow levels at various points within the arteries. A probe about the size of a human hair is inserted into the arteries and relays details that tell doctors where and how the blood flow is impeded.

The report states that the information also helps doctors measure the effectiveness of drugs and treatments and eliminates the need for surgeries that are most costly and dangerous.

Kentucky Center Named Outstanding Rural Practice

Saint Claire Medical Center, in Morehead, is the 1993 National Rural Health Association Outstanding Rural Practice. The award recognizes a community-oriented rural health care delivery practice that has improved access to rural people through innovative, comprehensive approaches. Factors taken into

consideration include outreach efforts, preventive health and educational programs, quality and efficiency of care, and strong community support and involvement.

Mandatory CME Regulations Published

The proposed regulation on mandatory continuing medical education for physicians has been published in the July 1, 1993, *Kentucky Administrative Register.* The 1992 House of Delegates adopted a recommendation that all physicians obtain 60 hours of CME over a 3 year period as a condition of licensure. The KMA CME Committee has worked with the Kentucky Board of Medical Licensure in development of the regulation. The CME Committee made several recommendations at its February 24, 1993, meeting, which were approved by the Board of Trustees at its April 1993 meeting and sent to the Kentucky Board of Medical Licensure for consideration.

The proposed regulation is as follows:

Section 1. Continuing Medical Education. After January 1, 1994, every licensee is required to submit, with his or her annual licensure renewal form, verification of satisfactory completion of a program of continuing medical education. The following are the requirements for licensees:

1. Licensees shall complete a minimum of sixty (60) hours of continuing medical education every three (3) years, with thirty (30) of said hours being certified in Category 1 by an organization accredited by the Accreditation Council on Continuing Medical Education. Verification of such attainment shall be submitted to the board before April 1 of a given year and can be submitted in the following ways:

a. Submit evidence that the licensee has received the American Medical Association's (AMA's) "physician recognition award" (PRA) or the American Osteopathic Association's (AOA's) "osteopathic physicians' recognition award" (OPRA) and that such award is in effect at the time a license is renewed.

b. Submit verification that the licensee has completed continuing medical education requirements of any specialty organization which are recognized by the AMA or AOA as at least equivalent to their recognition awards, and that such certification is in effect at the time a license is renewed.

c. Submit verification that the licensee is in or has been in an approved postgraduate training program. Each year of postgraduate training is equivalent to fifty (50) hours of continuing medical education.

2. The board may grant an extension of time to a physician who for sufficient cause has not yet received continuing medical education certification.

3. A minimum of two (2) of the continuing medical education hours shall be in HIV/AIDS courses approved by the Cabinet for Human Resources pursuant to 201 KAR 2:160.

4. Each year, with the application for renewal of an active license to practice medicine, the board will include a question which requires the licensee to certify by signature that he or she has met the continuing medical education requirements for the three (3) year cycle. In addition, the board may randomly require physicians submitting such a certification to demonstrate satisfactory completion of the continuing medical education requirements stated in his or her certification.

5. The licensee who fails to timely complete the continuing medical education requirements, or who fails to obtain an extension of time as outlined in Section 4 of this administrative regulation, shall be fined a minimum of $200 and allowed six (6) months to come into compliance. After the six (6) month period of time, should the licensee still be in noncompliance, his/her license shall be immediately suspended until such time as verifiable evidence is submitted indicating completion of the continuing education requirements.

(6) Under no circumstances will waivers be granted from the requirements of this regulation.

Physicians Should Use Only Approved Exam Gloves, Says FDA

A recent Food and Drug Administration study revealed that physicians are often unaware of an important difference between regular latex gloves and latex examination gloves. Under the federal Food, Drug and Cosmetic Act, latex examination gloves are considered medical devices subject to FDA inspection. Latex examination gloves must pass FDA tests for defects including leaks, tears and embedded foreign objects. Latex gloves, according to the FDA, are not medical devices. They are, therefore, not inspected by any government agency, nor labeled for intended use. Because of that, the FDA warns that latex gloves may not provide protection for health care workers or patients. The agency urges physicians and other health care workers to use only latex examination gloves for handling patient, patient exams and patient body fluid samples. Latex examination gloves may be labeled "exam gloves," "patient exam gloves," or "intended for medical use."

Kentucky Medical Insurance Company's "Excellent" Rating Reconfirmed for 1993

Kentucky Medical Insurance

Company has received notification that its A-(Excellent) rating from A. M. Best Company has been reconfirmed for 1993.

The A. M. Best Company assesses insurance companies' financial health and ability to meet policyholders obligations. Best cited Kentucky Medical Insurance Company's continued profitability, adequate capitalization and liquidity position as major factors in the renewal of their A-(Excellent) rating.

The Kentucky Medical Insurance Company was founded by the Kentucky Medical Association in 1978 to provide stability to the medical professional liability market. **Richard F. Hench, MD,** Lexington, serves as Chairman of Kentucky Medical Insurance's Board of Directors.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Boyd

Carol H. Cooper, MD — D
1200 Central Ave #4, Ashland, 41101
1989, Marshall U

Richard E. Paulus, MD — C
2233 Montgomery #C, Ashland 41101
1973, U of Vermont

W. Bryan Rogers, III, MD — S
1200 Central Ave #5, Ashland 41101
1982, U of South Carolina

Valerie J. White, MD — PTH
2201 Lexington Ave, Ashland 41101
1984, Eastern Virginia Med School

Breathitt

Ayn D. Siegel, MD — P
PO Box 794, Jackson 41339
1984, Thomas Jefferson U

Daviess

Robert Z. Fialkow, MD — NEP
2818 Hillside Dr, Owensboro 42303
1972, SUNY, Buffalo

Joel A. Johnston, MD — FP
868 Pleasure Point W, Maceo 42355
1989, U of Kentucky

Fayette

Aparna V. Mankad, MD — AN
UKMC-Dept Anes, Lexington 40536
1970, Topiwala Medical College

Francis J. McDonnell, MD — AN
724 Kirkland Dr, Lexington 40502
1977, Trinity Col, Ireland

Floyd

Anthony C. Stumbo, MD — IM
3750 W Mountain Pky, Prestonsburg 41653
1989, U of Kentucky

Henderson

Kuldeep R. Pandit, MD — PUD
327 N Elm St, Henderson 42420
1979, Maulana Azad Med Col

Jefferson

Luyen V. Cao, MD — IM
3025 Stonebridge Rd, Louisville 40241
1985, Rush Medical College

B. Gordon Carnes, MD — FP
9822 3rd St Rd, Louisville 40272
1984, Ross U

Linda S. Geis, MD — PD
1305 Highland Ave, Louisville 40204
1989, Texas Tech

Robert E. Henry, MD — NM
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1963, Saint Louis U

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Gregory D. Sweeney, MD — EM
James V. Tobin, MD — R
Louie N. Williams, MD — PMR

DEATHS

John E. Dawson, MD
Alexandria
1904-1993

John E. Dawson, MD, a retired general practitioner, died May 4, 1993. Dr Dawson graduated from the University of Cincinnati College of Medicine Ohio in 1928 and was a life member of KMA.

Alvin B. Mullen, MD
Ft. Wright
1901-1993

Alvin B. Mullen, MD, a pulmonary disease physician, died June 7, 1993. Dr Mullen was a 1925 graduate of the University of Louisville School of Medicine and a life member of KMA.

Lincoln M. DeSouza, MD
Harlan
1930-1993

Lincoln M. DeSouza, MD, a urologist, died June 8, 1993. A 1954 graduate of Universidade Federal de Minas Gerais in Brazil, Dr De Souza was an active member of KMA.

Frank T. Smith, MD
Middlesboro
1932-1993

Frank T. Smith, MD, a general practitioner, died June 20, 1993. Dr Smith was a 1958 graduate of the University of Tennessee College of Medicine and an active member of KMA.

Edward M. Haick, MD
Louisville
1931-1993

Edward M. Haick, MD, a radiologist, died July 4, 1993. Dr Haick graduated from Northwestern University Medical School in 1961 and was an active member of KMA.

Edward E. Landis, MD
Louisville
1907-1993

Edward E. Landis, MD, a retired psychiatrist, died July 7, 1993. Dr Landis was a pioneer in the use of electric treatment and brain-wave devices in Kentucky and founded the EEG Department at the University of Louisville. A 1935 graduate of Northwestern University Medical School, Dr Landis was a life member of KMA.

Frank Lewis Duncan, MD
Monticello
1911-1993

Frank Lewis Duncan, MD, a retired general practitioner, died July 11, 1993. Dr Duncan graduated from the University of Louisville School of Medicine in 1936 and was a life member of KMA.

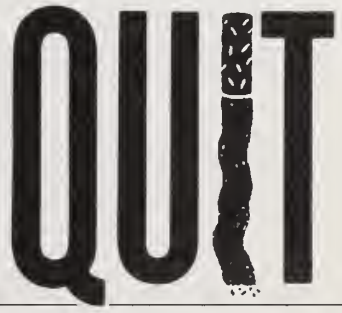
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25-29 — American College of Occupational and Environmental Medicine (ACOEM), 1993 State-of-the-Art Conference, Fairmont Hotel, Dallas, TX. Contact: ACOEM. 55 W Seegers Rd, Arlington Heights, IL 60005; 708/228-6850; FAX 708/228-1856.

28-31 — 87th Annual Scientific Assembly of the Southern Medical Association; New Orleans, LA. Contact: SMA Registration Dept; 205/945-1840, 800/423-4992 or FAX 205/942-0642.

31-Nov 5 — 24th Annual Family Medicine & Primary Care Review; Hyatt Regency, Lexington, KY. 50 hrs Category I; Contact: OCME, University of Kentucky, Kentucky Clinic; Lexington, KY 40536-0284; 606/233-5161, or toll free, UK-MDs Physician to Physician Service 800/888-5533.

NOVEMBER

5-7 — Fifth Annual Infectious Disease Review Course, Hyatt Regency, Bethesda, MD. Sponsored by the Center for Bio-Medical Communication. 17.5 hrs Category I. Contact: Sylvia Razzo, Center for Bio-Medical Communication, Inc, 80 West Madison Ave, Dumont, NJ 07268; 201/385-8080; 800/231-0389; FAX 201/385-5650.

6 — Four State Neuroscience Conference; Cincinnati, OH. Sponsored by Mayfield Neurological Institute. Contact: Sheila Stuckey, Meeting Coordinator, Mayfield Neurological Institute, 506 Oak St, Cincinnati, OH 45219; 513/569-5251, FAX 513/569-5365.

14-18 — 97th Annual Meeting of the American Academy of Ophthalmology; McCormick Place, Chicago. Contact: The American Academy of Ophthalmology, Meetings Department, PO Box 7424, San Francisco, CA 94120-7424; 415/561-8500.

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6-10 — Southeastern Surgical Congress; Buena Vista Palace, Lake Buena Vista, Florida. Contact: the Congress Office, Suite 410N, 1776 Peachtree St, Atlanta, Ga 30309; 404/607-8958.

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CONTRAINDICATIONS

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Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12h}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli,* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class.

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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THE PRAVACHOL® DIRECTION IN LIPID MANAGEMENT

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Effective lipid management doesn't have to be tough



- Improves key lipids — significant reduction in LDL-C[1]
- Excellent safety profile
- Easy for patients — once-daily dosing, well tolerated
- Usual dose: 20 mg once daily at bedtime, with or without food

PRAVACHOL®

pravastatin sodium 20 mg tablets

PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

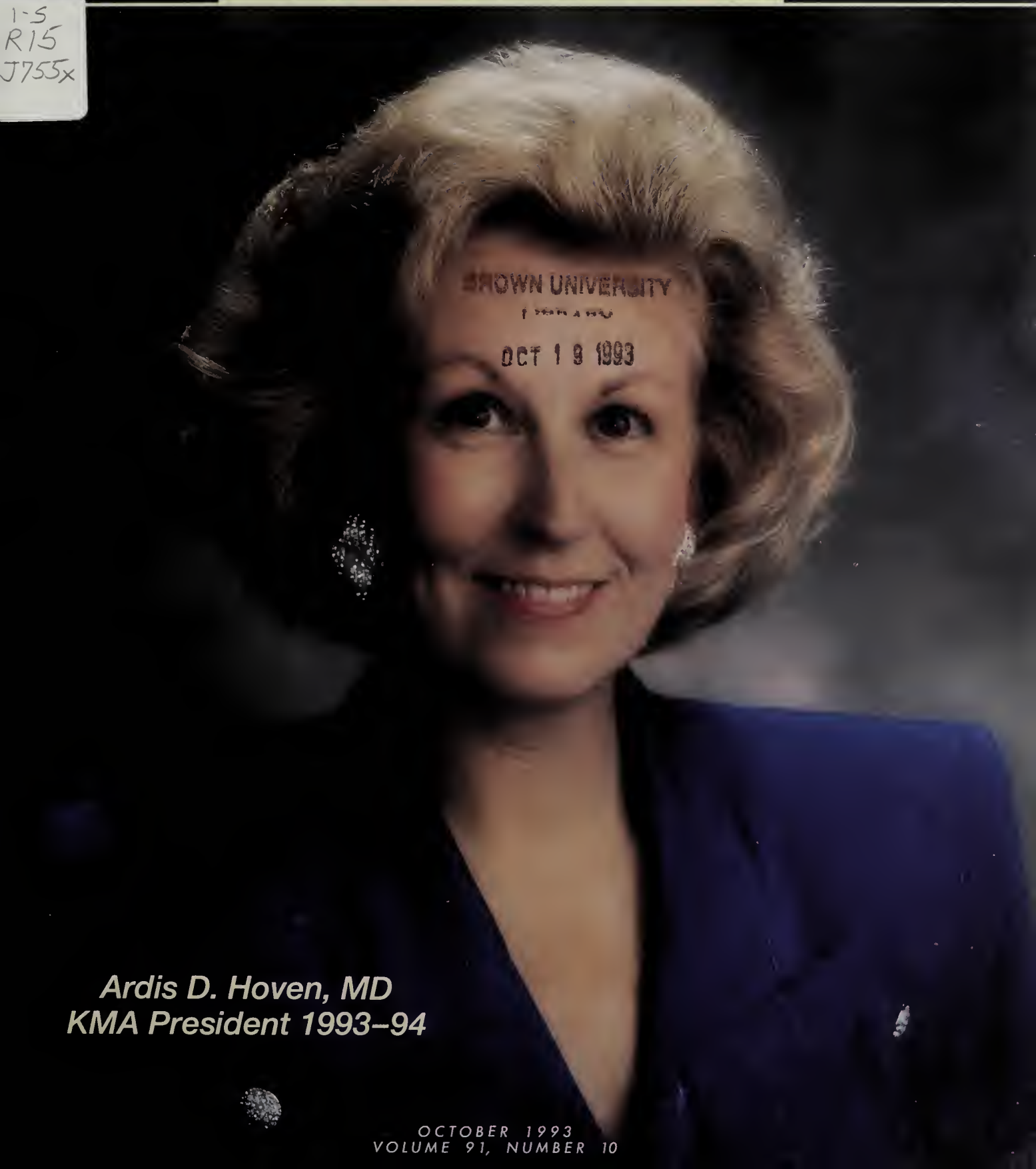
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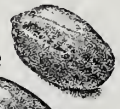
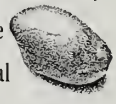
OCTOBER 1993
VOLUME 91, NUMBER 10

We expect you to make decisions our competitors make for you.

And we charge more.

Are we nuts?



Medical liability insurance companies are more than willing to make one  of your most important decisions for you. In fact, they insist on it. The decision on whether to go  to court or settle a claim. Yet insurance company lawyers who make that decision have their company's bottom line — not your reputation — as their only concern. And a decision to settle can put your reputation at risk. Permanently. Because even if you're right as rain, you look wrong. Guilty. So our policies guarantee we don't settle  unless *you* want to settle. Which is very likely one reason we're sponsored by the Kentucky Medical Association. As well as being the leading provider of medical liability insurance in our area. For complete information, call 1-800-467-1858. The decision  to call — like the decision to settle — is yours.

KENTUCKY MEDICAL INSURANCE COMPANY

Discover The Elegance Of A Hybrid



At first glance, it's the ***beauty*** of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its ***elegance*** becomes apparent—a gentle blend of softness and strength.

At first glance, it's the ***enhanced performance*** of Vaseretic that catches the eye. But study Vaseretic more closely, and its ***elegance*** becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid ***blending of tolerability and power*** that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

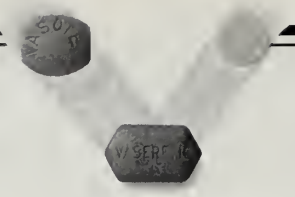
VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)



USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General; Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy: Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5.6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate; Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent pre-existing renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients. Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69®) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions; Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide: When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings: Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia, atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported, a causal relationship to enalapril has not been established. *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympathicolytic and mydriatric. It may have activity as an aphrodisiac.

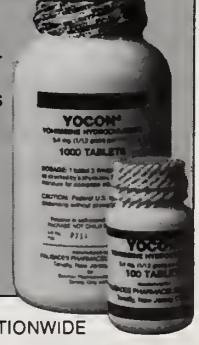
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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1994 International Conference on Physician Health
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"Stress: The Profession, the Family and You"

The 1994 International Conference on Physician Health, co-sponsored by the American Medical Association, the Federation of State Medical Boards, the Canadian Medical Association, and the Federation of Medical Licensing Authorities of Canada is scheduled for September 16-20, 1994, at the Ottawa Westin Hotel.

Ottawa is Canada's capital and offers many national museums, over 60 miles of bicycle paths, hiking in Gateneau park, squash courts and swimming at the hotel and golf nearby.

The conference will provide a forum for practitioners and researchers to present recent findings and innovative treatment and education programs in physician health. This conference will address a range of issues, such as AIDS, HIV, problems related to aging, mental illness, substance abuse and physical disabilities and limitations, including those caused by general medical conditions. Possible topics for presentation include: presentation and treatment of health problems among physicians, the impact of disorders on physicians' families and practices, medical-legal issues facing hospital administrations and licensing boards, and material on health promotion and disease prevention. *Abstracts which address issues related to these topics (i.e., prevention, diagnosis, treatment, rehabilitation), but not dealing specifically with physicians are also welcome.*

Three types of presentations regarding these physician health issues are invited:

- **Poster Presentations**
 Written presentations of data-based research, epidemiological research, or program descriptions.
- **Paper Sessions**
 Oral presentation of scientific, data-based findings relative to the topic of physician health.

 Abstracts for poster presentations and paper sessions should contain an introductory statement on the significance of subject matter. Description of methods, results, and conclusions should follow the introductory statement.
- **Workshops**
 Training or instructional presentations, designed to improve specific skills of persons who work in the area of physician health.

 Abstracts for workshops should contain information on the program's intended audience, goals, teaching strategies, and materials. Evaluation data should be summarized

Abstracts may not exceed 200 words. Any abstracts exceeding that length will be rejected. Abstracts should be typed, double spaced, and mailed (not faxed). Four copies of the abstract should be sent, along with one self-addressed, stamped envelope. All submissions must list the primary and secondary authors and their professional affiliations. Telephone number and address of primary author must also be included.

Submissions *must* be received by February 1, 1994.

Abstracts will be submitted for blind review. Abstracts will be judged on their applicability to the conference topic area and their scientific merit. The decisions of the blind reviewers will be communicated to the abstract's primary author by April 1, 1994.

All presenters are expected to register for the conference at the AMA member rate. We are unable to provide any financial support for presenters. Presenters will also be responsible for their own transportation and hotel expenses, as well as making all reservations for same.

Send all materials to:
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***COVER:** On September 29, 1993, Ardis D. Hoven, MD, an infectious disease specialist from Lexington, Kentucky, became the first woman ever to be installed as President in the 143-year history of the Kentucky Medical Association. Dr Hoven's Inaugural Address begins on page 443.*

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Ardis D. Hoven, MD

Inaugural Address

Ardis D. Hoven, MD

"I would be remiss if I did not tell you that as the first woman to hold this position, I am greatly honored and challenged to work diligently and effectively on your behalf."

Thank you for the honor bestowed upon me as the 143rd President of the Kentucky Medical Association. The opportunity for service to the profession of medicine and to my peers is a very important part of my professional career. I am truly grateful for the challenges and the experiences which will come from this endeavor.

I am also indebted to those physicians who have preceded me in this office. Their leadership has provided a clear blueprint from which those of us who follow may continue in the spirit of the Kentucky Medical Association and achieve the objectives and goals we feel so important in the practice of medicine and in the lives of our patients.

Today I choose to speak of advocacy and unity. Two simple concepts, but truly imperatives for the KMA as it moves into another year of deliberations regarding health care reform in this state and other issues requiring the initiatives of physicians in the local community and at the state level. KMA and the physicians of the Commonwealth have clearly declared their position on a variety of issues encompassed by health care reform. Dr William Monnig in his inaugural address last year stated, and I quote, "The KMA is committed to meaningful health care reform. We can be a strong partner for those who want to create a cooperative process for health care reform." That commitment continues, along with the dedication to uphold the principles and ethics of the profession of medicine, and to dedicate ourselves to the best possible methods of practice and delivery of medical care in our state.

As we continue into this next year's agenda, I would suggest to you two measuring sticks or instruments by which we should evaluate and judge the elements being considered in the reform process:

- advocacy for our patients and all the people of the Commonwealth; and
- advocacy for the profession of medicine.

If the policies and procedures being considered do not meet our high standards in these two areas, we must boldly and candidly, but in the spirit of cooperation, speak out. We will repeatedly ask: "Does it meet adequately the needs of our patients?" and "Does it allow physicians to practice high quality, innovative medicine and provide

Inaugural Address

comprehensive care?" Inherent, however, in this attitude is the willingness to consider new methods and concepts enabling us to continue to render care and not being fearful of change, if it is in the best interest of our patients and the profession. We must avoid fossilization of our innovative and creative capabilities.

The KMA has a healthy tradition of patient advocacy. Many issues, in addition to a very strong voice for meaningful and financially responsible health care reform, have over the past several years been important to the citizens of the Commonwealth. KMA has taken the leadership position in promoting preventive care and other lifesaving initiatives, both in the community and in the legislature; we have spoken about and become involved in community awareness and education regarding domestic and interpersonal violence; we have debated, educated and legislated issues centered around HIV disease and directed our attention to the issues surrounding the infected health care worker.

The Kentucky Physicians Care Program remains an extremely important component of our indigent health care initiatives. We, the physicians, have spoken strongly in favor of a strong and independent Board of Medical Licensure, and we have supported actively the impaired physicians program — all ultimately benefiting our patients. These are just a few examples of our advocacy role.

Clearly, health care reform will continue for us to be a major agenda item, probably for several years to come. An incredible amount of energy and intellect has already been applied to this process, and we will continue to work on the behalf of our patients and our profession. Our ability to render excellent quality medical care in a fiscally responsible environment will be of foremost concern as we deliberate the issues.

The Task Force on Health Care Reform has completed its subcommittee work; the reports have been filed. With the provider tax in litigation, we must move on to the current proposals emanating from the subcommittees. We as physicians and the Kentucky Medical Association do understand the fiscal issues necessary for health care reform. We likewise understand where the excesses are and what can be done to relieve the problems if given the opportunity legally and politically. Price-fixing historically has not worked and will not work in the arena of health care. Discriminatory rates of reimbursement for providers of health care have for a long time been opposed by organized medicine for obvious reasons. "Packaged" health care for rural Kentucky cannot be the same as it is for the more urban areas. Solid tort and liability reform in this state must take place in order for meaningful health care reform to progress. This past year we have benefited from strong and effective leadership. Dr William Monnig in his role as President strongly and precisely stated and debated our positions and concerns. Dr Russell Travis, as Chairman of the Board of Trustees, with a great wealth of knowledge led us cautiously through the maze of information and political activity and provided powerful insight into the problems ahead.

"Never before has the issue of unity among physicians and organized medicine been so important as it is now. There is simply no room for polarization or fragmentation. The problem solving skills we all possess, our abilities to communicate with one another and our dedication to a very high and special calling should enable us cohesively and confidently to move forward."

In his inaugural address as the 148th President of the American Medical Association, Dr Joseph Painter spoke of three constants in medicine:

- the first — scientific excellence resulting in high quality care;
- the second — the patient/physician relationship which is the ethical cornerstone of our profession;
- the third — use of our problem-solving skills.

Those problem-solving skills which we use routinely and daily must be applied to health care reform with physicians as partners in the process. It is vitally important that we protect these three constants.

In June, Dr James Todd at the opening session of the AMA House of Delegates stated, "Unity within our professional family is a key to the destiny of the house of medicine." Never before has the issue of unity among physicians and organized medicine been so important as it is now. There is simply no room for polarization or fragmentation. The problem-solving skills we all possess, our abilities to communicate with one another, and our dedication to a very high and special calling should enable us cohesively and confidently to move forward. Henry Ford once said, "Don't find the fault, find a remedy." General George Patton pronounced, "If everyone is thinking alike, then somebody isn't thinking."

There is plenty of room under the tent for divergent views — we learn from one another. There is adequate

"... I would suggest to you two measuring sticks or instruments by which we may evaluate and judge the elements being considered in the reform process: advocacy for patients and advocacy for the profession of medicine. If the policies and procedures being considered do not meet our standards in these two areas, we must both candidly and in the spirit of cooperation speak out."

time for all to be heard and the issues debated — we must respect and consider all views and democratically resolve the problems. The democratic process is truly alive and well on the floor of the House of Delegates and in the reference committees of this our Annual Meeting — so vital to the life of organized medicine. I challenge all physicians to be involved constructively and to contribute in a meaningful way to the many initiatives being undertaken at the local community level and at the state level. One of my responsibilities to you as President of KMA will be to keep us all on our feet!

Repeatedly we hear that the medical profession has somewhat faltered in its objectives and the public's perception of us is not precisely as we would like it to be. This is a painful and sensitive issue, but nonetheless one we must confront. Why has this occurred? What messages do we truly deliver about ourselves as physicians and the medical profession as a whole? Dr John Ring, Past President of the American Medical Association, defined medicine's professionalism as that dedication to competence, compassion, and moral accountability. We as individuals and as the Kentucky Medical Association must continue to carry these attributes as a banner for all to see.

Thank you for giving me the opportunity of serving you as President of the Kentucky Medical Association. I would be remiss if I did not tell you that as the first woman to hold this position, I am greatly honored and challenged to work diligently and effectively on your behalf. It is so important that as physicians we serve as role models and leaders to those who will come behind us. It is equally important that we leave them a legacy of committed service and solid foundations upon which they will continue the practice of medicine.

As we move into another year of intensive activity and committed endeavors on behalf of our patients and our profession, I ask for your support, your energies, your opinions, and your thoughtful ideas. I then ask of you that you commit to a strengthened and more powerful Kentucky Medical Association.

Presented by
Ardis D. Hoven, MD
as she assumed the
presidency of the Kentucky
Medical Association
on September 29, 1993

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Patterns of Chronic Granulomatous Disease

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We report the clinical course of an adult patient with chronic granulomatous disease, an inherited disorder of neutrophil function that is generally limited to the pediatric population. The biochemical and functional disorders of the neutrophil in chronic granulomatous disease are examined. The mode of inheritance and expression of this disease is profiled to aid the clinician who must consider this diagnosis in the adult patient with recurrent infections.

One mechanism of host defense against bacterial disease is the killing and digestion of microbes by polymorphonuclear leukocytes. These white blood cells are mobile and may be aggressively recruited after chemotactic stimulation of resident phagocytes. This unidirectional movement of granulocytes in response to mediator stimulation is term leukostasis. After arriving at an infectious inflammatory environment, proper granulocyte function requires that microbes be engulfed, a process termed phagocytosis. Finally, the cell must provide an intracellular milieu that adequately promotes bacterial death.

Studies of children with recurrent infections have identified a subset of patients with normal humoral and cell-mediated immunity whose neutrophils lack effective bactericidal activity. One such condition, chronic granulomatous disease (CGD), is known to be an inherited defect.[1] Over 100 pediatric patients with this type of leukocyte dysfunction have been profiled in the medical literature during the past 20 years. Very few adults, however, have been described with this condition.

Newer information regarding CGD suggests that it is not a single disorder, but a syndrome of heterogenous defects in the leukocyte's enzymatic cascade required for effective bacterial killing. There are variable modes of inheritance and expression, although the eventual clinical profile of recurrent and progressive infection remains similar. As serologic confirmation expands our understanding of the multiple potential sites of breakdown in the granulocyte's metabolic response to bacterial, ingestion, it is apparent that the diagnosis of CGD should be considered in the differential of persistent or recurrent infection of the older population.

We present an adult patient with CGD whose major medical problem involved recurrent infection of the lower respiratory tract with progressive lung destruction. We review the current concepts responsible for the impaired bactericidal capacity in CGD and discuss diagnostic and treatment strategies.

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Case Report

The patient, a 27-year-old white male, was admitted with a low grade fever, pleuritic chest pain, and a cough that was productive of a purulent sputum. The sputum was intermittently tinged with blood. Six days of outpatient treatment with erythromycin had failed to improve his complaints.

A history of multiple and persistent lower respiratory tract infections could be established, beginning during his adolescence. Fourteen months prior to this admission, he had a left upper lobectomy to relieve bronchiectasis that had resulted from recurrent respiratory infections. He had a cigarette smoking history that totaled 12 pack-years. He denied any known exposure to tuberculosis. The remainder of his review of systems as well as his family history was unremarkable.

He was cachectic and pale. His vital signs reflected mild respiratory distress with a heart rate of 108/min and a respiratory rate of 22/min. Coarse rhonchi were present in both lung fields. Despite the tachypnea, the patient altered his breathing pattern in order to splint the left hemithorax. A well healed thoracotomy scar was evi-

dent and nontender. Despite the patient's tachycardia, an increased splitting of the second heart sound was detected. The pulmonary component of the second heart sound was accentuated. Digital clubbing was noted. The remainder of his physical examination, including a detailed search for lymphadenopathy, was normal.

Pertinent laboratory data included a PaO_2 of 54 torr, a $PaCO_2$ of 36 torr, and a normal pH. His white blood cell count was 13.1/mm3 and contained 75% granulocytes, 5% band forms, 13% lymphocytes, 5% monocytes, and 2% eosinophils. Tests of liver function, renal function, and hemogram were normal. Antibodies for HIV were absent. Gram's stain of the sputum revealed numerous leukocytes, but no predominant microorganism.

Bilateral upper lobe cavitary disease was apparent on admission chest radiographs. Compared to radiographs done 1 year earlier, the changes suggested progressive and ongoing destruction of both upper lobes.

The patient remained febrile in the hospital in spite of the administration of combination intravenous antibiotics that provided reasonable empiric therapy for community acquired pneumonia. Consideration of *Mycobacterium* tuberculosis or fungal infection prompted fiberoptic bronchoscopy. *Pseudomonas cepacia* and *Aspergillus fumigatus* were recovered by bronchoalveolar lavage. Trimethoprim-sulfamethoxazole and ceftazidime were instituted with subjective improvement.

Further investigation showed that serum immunoglobulins and complement components were normal. T-cell and B-cell lymphocyte count and function were normal as assessed by phytohemagglutinin and conclavin A stimulation tests. The slide method for NBT dye reduction failed to show reaction or precipitation when the patient's leukocytes were stimulated with endotoxin. Additional tests were performed at a reference laboratory to further quantitate the defect in neutrophil function. These included C14-1-glucose utilization, superoxide radical generation, chemiluminescence generation, and protein iodination. Each function was impaired, and the diagnosis of CGD was confirmed.

The patient was discharged from the hospital and continued on daily oral trimethoprim and itraconazole. Evaluation for possible bone marrow transplant was arranged. The use of subcutaneously administered interferon-gamma was proposed, but the patient has refused this option.

Discussion

Appreciation of the various forms of CGD requires an understanding of normal granulocyte metabolism and the modifications that occur during phagocytosis to bring about bacterial death. A resting leukocyte regulates its intracellular metabolism of oxygen and glucose via the Krebs cycle to produce a variety of polypeptides that are stored either in the cytosol or the cell membrane. When exposed to an appropriate stimulus, these polypeptides are recruited to act in concert to produce oxidizing agents that are effective microbicidals.

This coordinated antimicrobial action requires a dramatic shift of glucose metabolism to the hexose monophosphate shunt, a process that is dependent on a continuing availability of oxygen.[2] A 10-fold rise in the activity of the hexose monophosphate shunt allows a glucose and oxygen uptake increase that results in the accumulation of intracellular vacuolar hydrogen peroxide (H_2O_2) and superoxide radicals (O_2-). The observation that increased amounts of oxygen were being consumed during microbe phagocytosis led investigators to apply the term "respiratory burst" to this cellular activation. More recent publications, however, use this term to refer to the adequate production of O_2-, which is the precursor of all other active antimicrobial oxidants.[3]

The leukocyte membrane contains a polypeptide oligomer with the potential to act as an enzymatic catalyst in the one electron reduction of oxygen (O_2) to a superoxide radical (O_2-). Under the proper stimulation, this reaction can occur at the expense of NADPH. The enzyme is alternatively labeled "NADPH oxidase" or the "respiratory burst oxidase." To enhance the catalytic activity of the oxidase in the membrane of human granulocytes, additional peptide components are incorporated into the membrane from the cytoplasm. In effect, the true respiratory oxidase burst is the culmination of the interaction of several distinct membrane and cytosol components (Table 1). The result is increased H_2O_2 and O_2- that interact with the normally present intracellular myeloperoxidase to iodinate and kill microbes.[4]

Formation of the membrane NADPH oxidase requires cytochrome b-558 which is a NADPH-binding flavoprotein, as well as several different cytosolic proteins. It has now been demonstrated that a lesion anywhere in the biochemical pathway of O_2- production can lead to the clinical

expression of CGD.[5] Deficiencies in cytochrome b or of the various cytosolic proteins have been identified as inherited disorders characterized by the failure of phagocytic cells to produce superoxide upon the ingestion of microorganisms. The disorder is now classified into subtypes depending on the mode of genetic transmission (X-linked or autosomal recessive) as well as the presence or absence of cytochrome b-558 (Table 2).

In normal leukocytes with increased oxidative metabolism, the colorless and soluble chemical nitroblue tetrazolium (NBT) has a high affinity for the hydrogen ions and will change form to a dark blue precipitate, NBTH. This simple test allows clinical confirmation of the presence of the increased hydrogen peroxide, an important product of the oxidative metabolic shift associated with effective phagocytosis.

The granulocytes and macrophages of patients with CGD do not respond to bacterial challenge with a respiratory oxidase burst. There is no increase in oxygen uptake and only a minor shift of glucose metabolism to the hexose monophosphate shunt. There is little significant accumulation of H_2O_2 and O_2-. Therefore, the NBT test will be negative.

The natural history of CGD is best demonstrated by patients with the X-linked inherited abnormalities of cytochrome b-588. During infancy, affected males typically develop eczema around the mouth which progresses to granulomatous lesions. Cervical adenitis, recurrent bronchopneumonia, and osteomyelitis follow. Interestingly, these children are relatively resistant to infection by hydrogen producing bacteria such as streptococci. More troublesome pathogens such as *Staphyloccoccus* and *Serratia* are particularly invasive. Eventually overwhelming infection with *Salmonella, Nocardia,* or *Aspergillus* accounts for the majority of deaths.

The clinical picture of patients with inherited deficiency of other components of the "respiratory oxidase burst" cascade are generally expected to have clinical courses similar to that described above. Nevertheless, the difference in the mode of inheritance may produce "variant" phenotypes. Some individuals with a small residual level of cytochrome b and O_2- production may have a milder disease expression. Likewise, there is evidence that "variant" subgroups of autosomal recessive CGD may exist since the defect may range from a partial gene deletion to complete single-based alterations.[6]

Table 1. The known protein components of the phagocyte-specific respiratory burst complex (NADPH-oxidase activation)

Membrane cytochrome b-588 (alpha & beta subunits)
Membrane protein gp91-phox
Membrane protein p22-phox
Cytosol protein p47-phox
Cytosol protein p67-phox
2 additional cytosolic cofactors remain incompletely characterized

Table 2. Classification and incidence of the defects causing CGD.

X-linked		Autosomal recessive	
(56%)		(6%)	
cytochrome b	absent	cytochrome b	absent
gp91-phox	absent	p22-phox	absent
		(33%)	
		cytochrome b	present
		p47-phox	absent
		(5%)	
		cytochrome b	present
		p67-phox	absent

The mothers of patients with X-linked inherited CGD are "carriers" who show only 50% normal bactericidal capability. Although they rarely have difficulty with infection,[7] some of these women may have an increased frequency of discoid lupus erythematosus.[8] Since X-linked CGD maps to a single locus on the short arm of the X chromosome, genetic mapping provides a tool that may serve to identify carriers.[9]

Long-term oral antimicrobial prophylaxis is advisable in the care of the patient with CGD. Trimethoprim-sulfamethoxazole appears to decrease the incidence of bacterial infections without increasing the incidence of fungal infections.[10] Cotrimoxazole has also shown good intracellular penetration and activity against *S. aureus* and enterobacteria. The role of the oral imidazole compounds for the prevention of fungal infections has not yet been determined.[11]

Pharmacologic alteration of phagocytic oxidative metabolism resulting from sustained administration of recombinant interferon-gamma can reduce the relative risk of serious infection by as much as 70%.[5] The subcutaneous administration of this agent improves the respiratory burst

in the autosomal recessive cytochrome b-positive CGD. While there is not a significant enhancement of superoxide production with this agent in X-linked or cytochrome b-negative CGD, bactericidal activity of both neutrophils and monocytes can be shown.[12] Nonoxidative bactericidal pathways are apparently stimulated by this treatment.[13] The agent's full influence on the oxidase components are not fully understood.

Bone marrow transplantation has been considered for correction of some genetic diseases. Histocompatible allogenic bone marrow transplantation has been cited as a method to ameliorate CGD. Likewise, autologous bone marrow transplantation after insertion of a normal gene in vitro has been attempted with variable success.

In summary, CGD is a term for a group of inherited disorders with heterogenous phenotypic profiles characterized by chronic and recurrent infection. Blood neutrophils, monocytes, and eosinophils are unable to manufacture microbicidal oxidants necessary to kill catalase positive bacteria. Increased understanding of the many components of the "respiratory burst" and their mode of inheritance help the clinician appreciate the variable expression of this disorder and anticipate milder expressions of the disease outside the pediatric population.

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Cerebral Hyperperfusion Syndrome: An Etiology of Seizures Following Carotid Endarterectomy

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Cerebral hyperperfusion syndrome after carotid endarterectomy is an uncommon but distressing complication. Findings in nearly all these patients include the presence of ipsilateral high-grade carotid artery stenosis, postoperative ipsilateral headache followed by seizures, and transient neurologic deficits. It appears to be caused by the loss of autoregulation within the brain, usually occurring between 5 and 7 days postoperatively.

Cerebral revascularization by carotid endarterectomy has in the past and continues to generate considerable debate. The basis of this debate is the risk of neurologic complications associated with carotid endarterectomy compared to those managed medically.

Neurologic complications associated with carotid endarterectomy that occur during operation are from either embolization or inadequate protection in those with marginal perfusion of the brain. Complications which appear in the immediate postoperative period (hours to days) are most likely ischemic in nature, from carotid artery occlusion or embolization. In a small number of patients, transient postoperative neurologic dysfunction occurs from cerebral *hyper*perfusion instead of *hypo*perfusion. This is an uncommon, but distressing, complication occurring in 0.4% to 1.0% of all carotid endarterectomies.[1-4]

Nearly all patients with this syndrome have ipsilateral high-grade carotid artery stenosis, postoperative ipsilateral headache followed by seizures, and transient neurologic deficits.[1-10] In even fewer cases this syndrome progresses to intracerebral hemorrhage with permanent neurologic deficits or death.[4, 5]

This report is of two cases in which transient neurologic events compatible with cerebral hyperperfusion syndrome occurred 10 days postoperatively from carotid endarterectomy.

Case Reports

Case 1 — A 61-year-old hypertensive male was found to have a critical stenosis of the right internal carotid artery on duplex scan during evaluation of asymptomatic bilateral carotid bruits. Angiography confirmed the presence of a 95% or greater stenosis of the right internal carotid artery, and less than 40% stenosis on the left.

After successful PTCA of a symptomatic right coronary artery stenosis, right carotid endarterectomy with dacron patch angioplasty was performed. The procedure was performed under general anesthesia and cerebral perfusion was maintained intraoperatively by use of a shunt. His neurologic examination postoperatively was normal. However, after having hypertension in the recovery room, he developed a large wound hematoma, which required evacuation. No technical problem was found. Again, his neurologic examination was normal postoperatively. He was discharged home on the third postoperative day with a normal neurologic examination, his hypertension well controlled, and without angina. He was kept on aspirin 325 mg daily.

On his tenth postoperative day he complained of having ipsilateral headaches, then developed a grand mal seizure and a postictal lateralizing hemiplegia, contralateral to the side of the endarterectomy, which lasted approximately 2 hours. He was given diazepam and phenytoin intravenously. Subsequently, his symptoms resolved. Duplex scan demonstrated a widely patent carotid endarterectomy without intimal defect, and CT scan, electroencephalogram (EEG), and 2-D echocardiography were normal. He was discharged on maintenance phenytoin without a neurologic deficit.

After 6 months of phenytoin, the patient was taken off the phenytoin without further seizures. Magnetic resonance imaging and EEG were normal prior to discontinuing the anticonvulsant

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medication. He continues to do well without neurologic dysfunction.

Case 2 — The patient was a 71-year-old male who had a right hemispheric transient ischemic attack about 1 week after CABG ×2. This was manifested by impaired speech, which resolved completely. One week later, he had another transient ischemic attack, this time with speech impairment and right eye amaurosis fugax. Again, there was complete resolution of the symptoms. Duplex scan was performed and this demonstrated a critical stenosis of the right internal carotid artery and moderate disease on the left. Angiography confirmed this, with the stenosis being greater than 95% on the right.

The patient was systemically heparinized and urgently taken to surgery where a right carotid endarterectomy with dacron patch angioplasty was performed. The procedure was performed under general anesthesia with maintenance of cerebral perfusion intraoperatively with a shunt. His neurologic examination postoperatively was normal. He was discharged home on the third postoperative day, doing well, and on aspirin 325 mg daily.

On the tenth postoperative day the patient had two grand mal seizures. He was given phenytoin intravenously to control these. CT scan of the head demonstrated motion artifact but no lesions, and EEG demonstrated diffuse slowing and an epileptogenic focus in the right temporal region with no definite evidence of a recent hemispheric lesion. 2-D echocardiography demonstrated mitral valve anulus calcification, akinesis of the distal one-half to one-third of the intraventricular septum, and no intracardiac masses or thrombi. Duplex scan demonstrated a patent endarterectomy site with minimal disease and no intimal defects. On further questioning, he stated he had right-sided headaches prior to the onset of the seizures. He was discharged on maintenance phenytoin with no further seizures or neurologic deficit. It is planned to maintain him on phenytoin for 6 months.

Discussion

The effects of changes in systemic blood pressure on nonischemic and ischemic cerebral cortex was described by Waltz[11] in 1968. In nonischemic cortex, cortical blood flow remained constant even during changes in systemic blood pressure. In ischemic cortex, cortical blood flow varied directly with systemic blood pressures from 35 to 120 mmHg. With pressures over 120 mmHg, there was usually no continued increase in cortical blood flow. However, in three animals in this study, increased systemic pressure did produce a continued increase in cortical flow. Waltz felt that cerebral ischemia impairs the autoregulation of cerebral blood flow.

There are two types of arteries in cerebral hemispheric circulation: conducting vessels (the internal carotid artery, its major trunks, and anastomosing smaller branches on the brain surface), and nutrient arterioles entering the brain parenchyma.[3,12] True cerebral autoregulation probably occurs in penetrating arterioles, modulated by the brainstem.[13,14] After endarterectomy, penetrating arterioles are able to function normally with a restoration of more normal tone (from one of maximal dilatation during ischemia) and autoregulation is again regained. It is also possible, as described by Bernstein et al,[5] that the impaired autoregulation will result in a state of hyperfusion until autoregulatory control is regained after some days.

In 1975, Leviton, Caplan, and Salzman[15] described headaches occurring after carotid endarterectomy, and hypothesized that they result from the loss of autoregulation. During the same year, Sundt, Sandok and Whisnant[1] reported six patients who had seizures after carotid endarterectomy. They postulated that these postoperative neurologic events were the result of increased cerebral blood flow.

Sundt et al[2] reviewed cerebral blood flow and electroencephalographic changes in carotid endarterectomies performed over a 10-year period. They found the most common causes of perioperative neurologic complications to be intraoperative embolization and postoperative hyperperfusion syndromes. Severe unilateral headaches occurred in six patients postoperatively. These patients had a mean increase in cerebral blood flow of 40ml/100gm/min. In five patients with intracerebral hemorrhage the mean increase in cerebral blood flow was 47ml/100gm/min, whereas in all patients with no neurologic complication, the mean increase was 1 to 5ml/100gm/min. They concluded that patients with a high-grade carotid stenosis and marked increases in cerebral blood flow perioperatively were at risk for postoperative neurologic dysfunction.

The postoperative course characteristic of hyperperfusion syndrome, ie, preoperative high grade stenosis, postoperative headache, and postoperative seizures on the side opposite to the carotid endarterectomy, has been reported by several authors.[3-7] Seizures, which were mostly fo-

cal motor in nature, were often difficult to control. Frequently, patients required the combined use of high doses of phenytoin, phenobarbital, and diazepam.[1, 4, 6-10]

When the studies of Reigel et al and others[1-10] are considered, a clear picture of cerebral hyperperfusion syndrome develops. Patients with this disorder often have a history of systemic hypertension and undergo carotid endarterectomy for severe chronic cerebral ischemia. Cerebral blood flow usually dramatically increases after endarterectomy. Postoperatively the patients complain of unilateral headache, and often have an ipsilateral cerebral deficit and/or seizures. Intracerebral hemorrhage may occur. The seizures most commonly occur between the 5th and 7th postoperative days, but have been reported to occur as early as the 3rd and as late as the 11th postoperative days.[3, 9] CT scans during this period are normal or show patchy edema. Duplex scans and/or angiograms are often normal, or in the case of angiography, increased perfusion may be seen. Cerebral blood flows measured postoperatively confirm continued hyperperfusion for days after surgery, with eventual normalization as autoregulation returns.[4]

Most patients are discharged on the third to fifth days after carotid endarterectomy, with some having their event after discharge, as in the case of our two patients. Guidelines for earlier diagnosis and management would be beneficial.

Careful preoperative examinations and thorough evaluation of the angiograms will help identify those with severe cerebral ischemia. Patients with severe stasis retinopathy, bilateral internal carotid stenosis of 95% or more, unilateral carotid occlusion and contralateral high-grade stenosis, and patients with unilateral critical stenosis and poor collateral cross-filling of that hemisphere should be recognized as being at risk for this syndrome. If perioperative use of antiplatelet agents or anticoagulants are indicated, they should be used cautiously.[4]

Severe unilateral headaches deserve further evaluation and careful management. Systemic blood pressure should be meticulously controlled, within the normal range. EEG is indicated to detect the presence of PLEDS (periodic lateralizing epileptiform discharges), which indicate an acute, localized focus of cerebral irritability.[4] CT scan may also be used to rule out intracerebral hemorrhage.

Berkowitz has reported anecdotal success with propranolol in managing severe unilateral headaches and averting seizures,[16] although Dolan and Mushlin,[6] and Kieburtz, Ricotta, and Moxley[10] have reported no benefit in its use.

If PLEDS are found on EEG, or seizures occur, anticonvulsant medications should be instituted. After resolution of the seizures, anticonvulsants are generally continued for 3 to 6 months, with repeat EEG prior to discontinuation of the medication.[11]

Although this syndrome is not fully understood, it is likely many vascular or neurologic surgeons have been confronted with a clinical picture compatible with hyperperfusion syndrome. Fortunately, the incidence of this syndrome occurs in only 0.4% to 1.0% of all carotid endarterectomies.

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Invasive Aspergillosis of the Central Nervous System

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Advancing technology permits aggressive medical interventions that are often lifesaving, yet place the patient's immune system in temporary jeopardy. During the interval of immunocompromise, physicians must maintain vigilance for opportunistic infection by saprophytic organisms such as Aspergillus.

Although the lung is the most common site of infection by this fungus, subsequent hematogenous dissemination with central nervous system involvement may occur. Currently, the majority of Aspergillus *infections of the central nervous system remain unrecognized until the patient's demise.*[1] *The clinical and pathological features of aspergillosis of the central nervous system are reviewed in order to promote earlier diagnosis and treatment.*

Aspergillus is the most common fungus in the environment, an ubiquitous saprophyte with at least 350 known species. Inoculation with *Aspergillus* most commonly occurs via inhalation of conidia, which are present in the soil, into the lower respiratory tract. This represents a dilemma for practicing physicians, since recovery of this organism from respiratory secretions in immunocompromised patients who are not neutropenic does not necessarily constitute disease. Likewise, only a few *Aspergillus* species are potential human pathogens.

If one of the species becomes established in the lung parenchyma, the mycelian form of the organism may invade the pulmonary vasculature. Angioinvasion is characteristic of *Aspergillus fumigatus* and *Aspergillus flavus*, the two most common human pathogens. The hematogenous spread results in predictable vascular injury that involves thrombosis and infarction in the affected end organ.

Disseminated aspergillosis is properly defined as concurrent infection of the lungs and at least one other noncontiguous organ. With its rich vascular supply, the central nervous system (CNS) is the organ most commonly involved in dissemination.[2] When disseminated aspergillosis is the primary cause of death, the most frequent terminal event involves intracerebral hemorrhage from fungal invasion, thrombosis, and infarction. Such hematogenous seeding of the CNS occurs in approximately 10% to 25% of patients with pulmonary aspergillosis.[3]

With the prolonged survival of patients with hematopoietic malignancies who are treated with immunosuppressive agents, *Aspergillus* infection is no longer a rare event. Nevertheless, CNS involvement remains difficult to document prior to the patient's demise. While numerous reports substantiate the successful outcome of treatment of CNS aspergillosis if recognized early, late diagnosis is almost always refractory to antifungal therapy.

We report a male patient with systemic lupus erythematosus who succumbed to disseminated aspergillosis with a CNS hemorrhage and uncal herniation. Understanding the clinical presentation of this disorder, as well as the problems in establishing a definitive diagnosis, is critical for evaluating the role of treatment and improving the patient's prognosis.

Case Report

The patient, a 44-year-old male, was electively admitted to the Louisville Veterans Administration Medical Center for evaluation of episodic disequilibrium. These spells were associated with nausea, diaphoresis, and occasionally small amounts of emesis. The symptoms would last from several seconds up to 10 minutes. The events were not positional nor associated with a specific trigger factor. The patient would feel as if he were falling towards his left side while the symptoms were present. He had lost approximately 10 pounds during the month prior to admission.

The patient had been diagnosed with systemic lupus erythematosus 15 years earlier in 1977. At that time he had myalgia, arthralgia, and

a right pleural effusion. The presence of an antinuclear antibody titer in the speckled pattern and the presence of biopsy proven membranous glomerulonephritis further reinforced this diagnosis. He was treated with Plaquinil and prednisone on a varying schedule until 1990. Reevaluation of his disease status at that time allowed discontinuation of these agents.

A Jehovah's Witness, the patient had never knowingly received blood products. He did not use alcohol or tobacco. There were no significant occupational or recreational exposures to toxins. He had no risk factors for HIV transmission.

He was initially alert, oriented, and afebrile. All vital signs were normal. A mild systolic ejection murmur was heard at the lower left sternal border, and had been identified on earlier admissions. Numerous areas of lymphadenopathy were palpated. A 1 cm diameter lymph node was present in the left supraclavicular region, another in the left posterior auricular chain, and bilateral inquinal nodes that were firm and nontender.

His hemogram measured the hemoglobin as 9.9 gm/dl, hematocrit as 29.3%, and the total white blood cell count at 13,000/mm3. The patient's ESR was 125 mm/hr. Double-stranded DNA antibody was positive at 2.1 u/ml. His SMA-18 and urinalysis were unremarkable. Electrocardiogram was normal. His chest radiograph was interpreted as showing a density in the right paratracheal area that was not present one year earlier (Fig 1).

His hospital course was marked by intermittent fevers to 101°F accompanied by night sweats and chills. An intradermal PPD was negative, but the patient had an appropriate delayed hypersensitivity response to other common antigens. Blood cultures were negative on several occasions. Several early morning sputums were negative for bacteria, mycobacteria, and fungi. Bone marrow biopsy was normal. Fungal serologies were negative. Despite the absence of risk factors, the patient consented to HIV testing and this was normal. T-lymphocyte subsets were normal and the helper/suppressor ratio was 1.3.

The right paratracheal lymphadenopathy was biopsied by mediastinoscopy. The left cervical lymph node was excised. Neither specimen was diagnostic for infection or malignancy.

The patient became lethargic, disoriented, and ataxic. No focal neurologic findings were present. A right cerebellar infarction or abscess with mild obstruction of the fourth ventricle was visualized on a CT scan of the head (Fig 2). Examination of the cerebral spinal fluid obtained



Fig 1 — PA chest radiograph shows new right hilar and paratracheal densities.

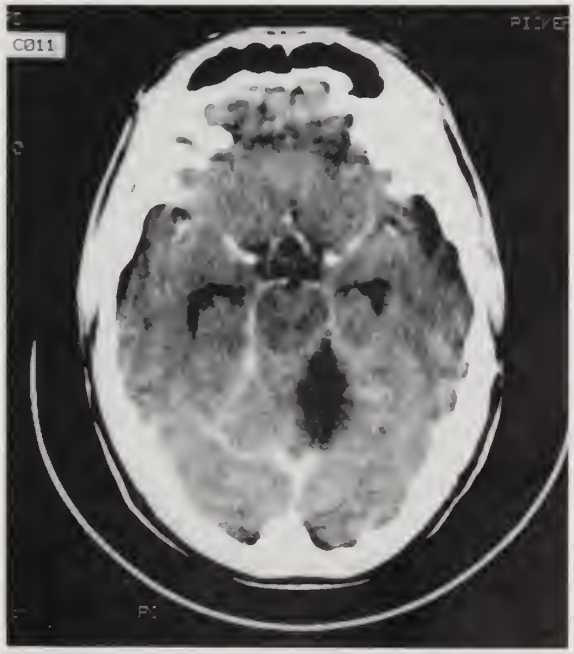


Fig 2 — CT scan of the head shows area of necrosis in the right cerebellum compromising the fourth ventricle.

from ventriculostomy was not helpful. At this point, the laboratory reported the growth of *A. fumigatus* from the culture of the excised left cervical lymph node. The patient, now obtunded, was returned to surgery for a left anterior cerebellar hemispherectomy. The patient's postoperative course was complicated by hypotension. His family continued to refuse blood products in concert with their religious beliefs. The patient expired 4 days after surgery.

An autopsy confirmed acute infarction of the cerebellum and rostral pons with right uncal herniation. The right paratracheal mass was felt to be consistent with an inflammatory pseudotumor. *Aspergillus* was recovered and identified by culture methods from this right paratracheal tissue. It was also cultured from the spleen, the liver, and several foci of the lung parenchyma.

Discussion

The true incidence of disseminated aspergillosis with CNS involvement is unknown. Although approximately 170 cases have been reported in the medical literature as of 1990,[4] this must certainly be an underestimate. The frequency of pulmonary aspergillosis is increasing as a terminal complicating infection as transplant services are expanded nationally.[5] Consequently, the frequency of CNS involvement should also increase.

Despite an increased awareness of the potential for disseminated fungal infection during periods of immunocompromise, central nervous system involvement with *Aspergillus* species has proved difficult to predict and diagnose. A 20-year review of autopsy records at The Johns Hopkins Hospital revealed only 17 CNS infections due to *Aspergillus* species.[1] Importantly, none of the patients was correctly diagnosed with clinical CNS aspergillosis before death. This observation represents a major limiting factor in epidemiology, as the majority of patients with a significant debilitating disease complicated by disseminated aspergillosis do not undergo postmortem investigation.

Although there are some case reports of invasive aspergillosis with CNS involvement occurring in immunocompetent individuals,[6] the majority of affected individuals have either comorbid disease or predisposing factors that interfere with the body's two major barriers to *Aspergillus* infection, the polymorphonuclear cells (PMNs) and the macrophages. The first line of defense is the lung's resident macrophages which have the capacity to kill the inhaled conidia. The PMNs are then recruited as the protectors against any developing *Aspergillus* mycelia. Both cell lines must be compromised before infection will occur.[7]

The presence of endogenous or exogenous elevation of glucocorticosteroids is often cited as a major risk factor, since corticosteroids suppress the phagocytic response of macrophages to *Aspergillus* and reduced recruitment of PMNs. Our patient was diagnosed with systemic lupus erythematosus (SLE), but had not used corticosteroids for 7 years. Nevertheless, some investigators associate deep fungal infections with SLE because of impaired cell-mediated immunity. Other investigators refute this hypothesis and cite the lack of data about the fungicidal properties of the phagocytic cells in patients with this disorder.[8] The autopsy findings in our patient demonstrated *Aspergillus* in organs with increased blood flow and parallels the distribution noted in other series of systemic aspergillosis.[2] This suggests that debilitating or autoimmune disorders may impart an independent risk (Table).

The use of marijuana may be an independent risk factor for Aspergillosis (H24). Approximately 52% of regular marijuana smokers become sensitized to the *Aspergillus* antigen. Invasive disease has been found to occur in these individuals who later required chemotherapy, radiation treatments, or both. In areas of the country where it is fashionable to encourage the use of marijuana as an anti-emetic for patients receiving chemotherapy, the remedial effects must be weighed against the possibility of infection with *Aspergillus*.

Direct inoculation of *Aspergillus* spores by intravenous injection of contaminated illicit drugs is another source of disseminated disease. Fortunately, this avenue of dissemination to the

Table. Diseases and predisposing factors associated with CNS Aspergillosis.

Malignancy: Lymphoma and Leukemia
Renal transplantation
Neutropenia
Exogenous corticosteroids
Long-term or multiple antibiotic use
Systemic lupus erythematosus
Chronic alcoholism
Diabetes
Endogenous hypercortisolism
Hepotic failure
Marijuana use
Intravenous drug abuse
Cardiovascular surgery for prosthetic valve implantation

CNS is relatively uncommon. In the rat model, it has been demonstrated that repeated large inocula of *Aspergillus* spores are needed to effect progressive brain damage. This may partially explain why CNS aspergillosis is not common among intravenous drug users.[11]

Disseminated aspergillosis with CNS involvement has been reported infrequently in patients suffering from AIDS.[11] The immunologic defect of T-helper cells is not a major host defense against *Aspergillus.* Other risk factors such as neutropenia, steroid use, intravenous drug abuse, and prolonged antibiotic use are generally present and increase the likelihood of aspergillosis. Invasive aspergillosis is not considered to be an AIDS-related opportunistic infection.[12]

Bloodstream inoculation of brain tissue favors the posterior circulation, usually resulting in multiple lesions, as well as involvement of the cerebellum.[13] The varied presentations of aspergillosis of the CNS include thrombosis with hemorrhage, multiple brain abscesses, isolated granulomata without abscesses, meningitis, meningoencephalitis, arachnoiditis, and subarachnoid hemorrhage.[14]

Granulomatous reactions are rare due to the patient's limited survival. At autopsy, solitary or multiple subcortical hemorrhagic infarcts are the most common lesions. Under light microscopy, a combination of coagulative necrosis and varied stages of hemorrhage are apparent. Adjacent intracranial vessels may show thrombosis by *Aspergillus* hyphae.

Importantly, the meninges are usually only focally infected in the areas adjacent to the subcortical lesion. Therefore, meningismus and signs of meningeal irritation are uncommon.[1] This pathophysiology also limits the utility of lumbar puncture and CSF analysis in confirming the correct diagnosis.

Given the tendancy for hemorrhage and abscess formation, it is common for patients with CNS aspergillosis to manifest signs and symptoms of a mass lesion with very little evidence of infection. Most commonly this will be a focal neurologic deficit, such as a hemiparesis from hemorrhagic infarction in the contralateral subcortical white matter. These lesions may cause pressure-induced tonsillar and/or transtentorial herniation as the patient's terminal event.[1]

Occasionally, focal seizures will be the presenting symptom or, as in our patient, a cerebellar symptom will predominate. Without treatment, the onset of the focal neurological deficit is quickly followed by confusion and disturbed consciousness.[1]

Diagnostic imaging includes radionuclide brain scanning, computerized tomography, and magnetic resonance imaging (MRI). MRI is the imaging modality of choice. When coupled with an injection of gadopentetate dimeglumine, it is more sensitive than CT for detecting diffuse intracranial *Aspergillus* infectious disease and cerebritis.[15] CT scan is neither sensitive nor specific in early disease and the characteristic ring enhancing abscess lesion is a late change in the evolution of intracranial aspergillosis. Although the cranial CT scan is expected to be abnormal, variable degrees of enhancement, lucency, and edema are seen which do not necessarily correlate with the extent of brain disease. Underestimation of the extent of tissue involvement by this imaging method is well documented.[16]

While serial determination of precipitant antibody titers may serve as a useful therapeutic and diagnostic indicator, debilitated patients are frequently unable to produce adequate antibodies, thus limiting the utility of serology to an adjunctive role. The specificity and predictive value of a single antibody titer remains low.

The only suggestive clues from CSF analysis of *Aspergillus* infection may be the presence of red blood cells and a slightly elevated protein, averaging 90 mg/dl. The WBC count is nonspecific and contains various distributions of polymorphonuclear and mononuclear cells. There are only nine cases reported in the medical literature in which *Aspergillus* was successfully cultured from the CSF.[1] Although *Aspergillus* antigens have been demonstrated in serum and pleural fluid, they have not been reported in CSF.

The diagnosis of invasive aspergillosis can be made with certainty only by demonstrating fungal elements in pathologic material and by repeated isolation of the fungus in cultures. In the context of a chronic debilitating disease, hematopoietic malignancy, or AIDS, the decision to perform a stereotactic brain biopsy will often present a marked dilemma for the clinician, the patient, and the patient's family.

If a biopsy is performed, diagnosis depends on recognition of the dichotomously angular branching septate hyphae infiltrating the brain tissue in a centrifugal pattern. The necrotic tissue remains at the center of the abscess and hyphae involve the advancing border of the abscess/hemorrhage. This characteristic pattern is enhanced by using the appropriate Gridley or Grocott's

methenamine silver stain.

It is imperative that the clinician understand that the *Aspergillus* organisms, identifiable morphologically in tissue samples, rarely grow on cultures despite use of a suitable medium.[2, 12] Treatment decisions cannot await culture confirmation without imposing a prohibitive delay in appropriate treatment.

Empiric treatment should be considered in the proper clinical context when morphologically appropriate organisms are identified in brain tissue samples or in the situation of a CNS mass lesion with a successful *Aspergillus* culture from a non-CNS tissue such as blood, urine, or lung secretions. The role of serologic tests are merely supportive.

Amphotericin B should be administered both intrathecally and intravenously, but has not always offered effective therapy. Based on in vitro synergism in killing activity, 5-fluorocytosine has been advocated as a useful agent for combination chemotherapy. The 5-flucytosine reaches significant tissue levels in the CSF with oral administration. While a ten-fold increase in killing activity is observed in vitro, this magnitude of synergism has never been proved in vivo. Nevertheless, given the dismal outlook of CNS involvement, this combination is frequently recommended. The addition of rifampin has been observed to increase in inhibition of growth of *Aspergillus,* but little increase in killing activity. To date there are no controlled clinical trials in humans using these drugs in combination. Numerous anecdotal success stories, however, foster continued interest.[17]

The newest group of orally administered antifungal agents includes imidazoles (ketoconazole), azoles (itraconazole), and triazoles (fluconazole). These agents may inhibit some strains of *Aspergillus* in vitro. Unfortunately, they cannot reach fungicidal concentrations that will allow effective systemic therapy for *Aspergillus* species in vivo.[7] Their role in combination therapy is still being tested.

Surgical extirpation of the cerebral lesions is usually undertaken only for diagnostic purposes. There have been only a few reports of successful surgical cure of cerebral *Aspergillus* abscess during the 30 years since the first report.[18, 19] These lesions were uniformly associated with contiguous spread of the organism from the ethmoid or sphenoid sinuses, rather than associated with disseminated disease. Generally, the surgical approach is precluded by the presence of multiple lesions, infarcted brain tissue, and the patient's underlying debilitation. Stereotactic drainage as an adjunct to antifungal therapy is considered on an individual basis.

Current prognosis is poor with a mortality of 70% to 80%.[18] This dismal outcome may reflect a relative resistance of the *Aspergillus* species to chemotherapy, the rarity of clinical experience with this infection, the lack of knowledge regarding the appropriate dosage and duration of antifungal therapy, or the presence of a significant underlying disease that initially predisposed the patient to this infection.

The single factor that appears to have the greatest impact on survival, however, is timely diagnosis with early institution of combination antifungal agents, stereotactic surgical drainage of any abscess, and discontinuation of further potential immunosuppression.

In summary, the most important feature in the diagnosis of invasive aspergillosis is recognition by the clinician of the patient profile and clinical setting in which *Aspergillus* flourishes. The high risk group generally requires the prolonged or continued use of antimicrobial agents, glucocorticoids, and cytotoxins. In this population, an acute neurologic event may be the earliest clue to the presence of disseminated aspergillosis. Early diagnosis and aggressive therapy may lessen the current high mortality rate.[1, 20]

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Business of Doing Practice

Magazines, newspapers, television, radios, and even the corner cafe fill some of their space with discussing health care. Americans transfer more than 12% of the gross national product to the health care industry. We physicians are part of that industry and therefore must define our competitors and adjust our BUSINESS OF DOING PRACTICE! I use these words to emphasize the mind-set that has to be formulated among us.

Saving dollars became the watchword in the late 80s, as the dollars supplied by industry and the government became fewer and more closely held. Deductibles increased, health care diets were imposed by the money watchers, and patients expected their sacrifices to silence the naysayers. Coverage had to be there, physicians available to salve wounds, and entitlements preserved. No luck, legislators and candidates sigh, and everyone looks for other sources of health care bleeding. Industry and government convene over long, paper filled tables and scream that the cost of services is too high. Now the meat of the matter is on the table and the entrepreneurs seize the meal with more efficient instruments. In real terms, laboratories run by large companies, some from our so called friends in pharmaceuticals, say they can deliver "services," not health care, for less money. Industry and the consumers look for the best deal to buy what they need. Since industry committed years ago to giving health benefits, they must factor these costs into their product prices. The marketplace forces these industries to compete with the lowest prices, and these health service purchasers seek the best deal. Now our problem is that physicians sell services such as body fluid analysis, x-ray taking, EKG monitoring, etc, to the consumer, to the insurance company, and to industry. If these laboratory services sellers can beat the physicians' prices, these dollars switch to the competitors! If these laboratory businesses can be more efficient, sophisticated, well equipped, and give cheaper services, then this work and the dollars spent for it will go to them.

This new laboratory industry, with its business types and its own physicians, is in this battle for financial gain, as are we OTHER physicians, in part. I add this hedge because most of us took our vows with the hope of taking good care of our patients, and living off some reward for our work. Nobody has come up with a substitute for the physician-patient relationship, intimate and personal, that often transcends these practical matters. Whether you call our patients consumers of health care and call us health care providers, the competition for their attendance to us is really not at stake. Time and again patients return to us, disgusted with impersonal medical "delivery systems." Many patients refuse to leave the comfort of knowing and interacting with their personal physician.

Stop talking about the years we put in, the hours we toil, and the financial debts and pressures we endure. As much as all of us feel like shouting out our defenses, the debate is not about what we make or deserve. It is about competition within the health care industry, of which we are a part. Our leverage is that we have the starter switches, we order the tests, we determine the need for surgery, for pharmaceuticals, for hospitalization, etc. Without us, these competitor laboratories have no patients upon whom to do their services. Industry, government, and insurance people are saying, deliver the service part of our care economically or give it to the competitor! You get advice from your builder but have someone else do the actual work, because he or she can do it better or cheaper.

I believe the payers want us to do the service work. We watch our labs, we supervise our technicians, we interpret the data and translate this information into care for our patients, right there on the front line. We make the calls late in the tiring day, not the distant lab or the computer paper streaming onto the floor. We should be compensated for this work, but not out of proportion to the cost. No other industry has the right or the chance to pick a price, independent of market forces. Realistically, market forces have hit us, and we know it. If we deliver our laboratory services cost effectively, our patients, industry, government, etc, will gravitate to us, not to the laboratory entrepreneurs.

It is time to negotiate, not finger point. Buyers of health services will listen to us, if we talk about this part of our health care delivery economically, not emotionally. Figure out if your business of delivering health services, not health care, is efficient and cost competitive. Armed with this data, talk to the insurers and industry representatives and respect their need to find a better system that helps them survive. Obviously this is a compromise, a required movement away from our independence and to some degree control of some income. Better to strike the deal that recognizes how good we can be, rather than a fiat about how bad we have been and about how we won't be given the opportunity to continue.

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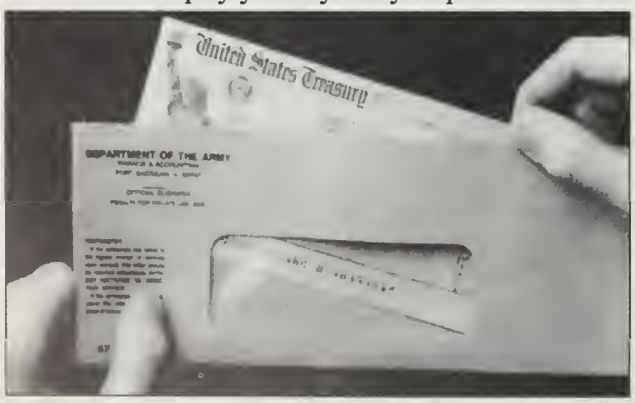
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A Message From AMA Alliance President Mary Hanson

Federated Membership
YOUR ONE CHOICE — THE BEST CHOICE

Our tri-level Alliance is a nationwide network of 60,000 members. A federated member is the male or female spouse of a physician who has chosen to be a member of the Alliance at the county, state, and national levels. You can help build this nationwide network by making this commitment today.

Our Alliance Page this month gives me an opportunity to introduce our national leader, AMA Alliance President, Mary Hanson.

YOUR ONE CHOICE — THE BEST CHOICE is to be a federated member of the Alliance.

— Gloria Griffin
KMAA President



Mary Hanson

The American Medical Association Alliance: physicians' spouses dedicated to the health of America. What opportunities our new name affords — the opportunity to reaffirm in a fresh and strong new way our unique partnership in medicine with our spouses, and the opportunity to use our tagline to describe what this strengthened partnership is all about: we *are* physicians' spouses dedicated to the health of America.

My trips throughout the country last spring provided proof of just how powerful this Alliance can be. I saw it in the enormously effective programs to prevent family violence and help its victims, in the conviction behind efforts to help shape health system reform, in the continuing support for medical education that made our contributions rise yet another year. I saw proof of our power in the enthusiasm of young members who bring to us the freshness of new ideas, in the sharing tradition of experienced members and the value of their input, in all of the wonderful members in between who faithfully sustain our quest for our goals.

All that I saw reaffirmed my belief that each of us can personally make this Alliance even stronger. We have the knowledge, the experience, the caring quality, and the creativity to make a difference. But if those resources are only talked about and one program after the other is developed and never effectively used, all of it is worthless. Instead, we must follow education with action. Our priority must be to use our Alliance to educate and to act on what we know is right. Because when thought and action are combined, the results are indeed powerful. As Dr William J. Mayo said, "When knowledge is translated into proper action, we speak of it as wisdom."

There is no one grand plan to solve the challenges that face us — the threats to the mental and physical well-being of our youth, the epidemic of family violence, the battle over health system reform. But that should not deter us from doing what we know is right, from having the wisdom to initiate proper action. Because every lasting change really happens one step at a time.

—Each of us can help one troubled child.
—Each of us can speak to one legislator.
—Each of us can buy one hour of medical education for the future.
—Each of us can reach out to one potential member to welcome in our midst.

And if each one of us takes any one step, we can be twice as effective in every area we pursue.

That is why my message to you is one choice, a choice that is from my perspective clear and non-negotiable. It is of the choice for all physicians' spouses to make that one small investment for a huge benefit to our communities and to us personally. I challenge all of us to use our wisdom and advantages to take action and make an impact on the people around us, on our communities, and on our future, so we become a powerful Alliance that achieves and even exceeds our goals.

My best wishes for a successful year.

Mary Hanson
AMAA President



Ardis D. Hoven, MD KMA President 1993-94

She is honored, and with delight *she* accepts the leadership mantle of the Kentucky Medical Association — Ardis Dee Hoven, MD, the first woman to ever serve as President of the Kentucky Medical Association in its 143-year history, as well as the first woman to have ever served on the Board of Trustees.

"I'm very honored. Clearly, it's a milestone. I'm absolutely ecstatic that I'm to be the first woman President," exclaims Dr Hoven. Her excitement, however, is tempered with the realization that the honor is not without a price. "It's a double-barreled shotgun. Looking at one barrel is the entire responsibility of being President and following in the footsteps of some incredibly strong and wonderful people who have led us through some very difficult times, and the other is that of being the first woman in the position. I anticipate being observed with a much finer microscope, but I have been aware of that most of my career. This presidency will be watched. It will be remembered."

Admirable, articulate, aristocratic, affable, approachable, accommodating, attractive, *authentic* . . . are words that describe Ardis Hoven, MD. Arrogant, assuming, antagonistic, affected . . . are words that do not. She has innate leadership qualities — sincerity, inspiration, fervor. A master at taking complex issues, letting everyone say their piece, and bringing it all together in a clear and concise manner, Dr Hoven comes to the KMA leadership with a desire to be a facilitator, a consensus maker.

"I'm not an iron fist person. To bring people to the table with multiple skills and interests and have them go away having made contributions in producing a product that we're all happy with — that's what I do best. I have strong opinions, but hopefully I'm able to control those to the point where I can let other people exert their opinions and then as a facilitator make the end product in the best interest of everyone. How I got to that position, I'll never know, but that's the way I work most effectively."

Gender and Accomplishment

Growing up, accomplishment in her life was nurtured and encouraged with no thought to gender. "Never in my entire career have I thought that being a woman would keep me from doing anything that I wanted to do. Part of that is a spinoff from my parents. They told me that I could do anything I wanted to . . . and I believed them. Isn't that incredible? At the age of 8, I knew I wanted to become a physician. My father was a minister, so I thought I should become a medical missionary." With misting eyes, Dr Hoven revealed the response of her father, a nationally-known and highly regarded clergyman, now deceased. "He promptly sat me down and told me that I would have greater opportunities to serve at home than in other parts of the world, and I think that message held true." Her mother, a lady Dr Hoven describes as a vibrant personality with a very keen mind, still provides strong encouragement and support for her pioneering daughter.

"My gender has not been an influence one way or the other," says Dr Hoven as she discusses her professional achievements. "My peers have not treated me differently because I am a woman. Once I proved my sincerity about what I was doing, the opportunities came. Many women are advancing in medical politics. To me, this is not a 'gender specific' issue, but a 'gender interest' issue. If you get involved early and understand the mechanisms and systems and you are contributing, then you will succeed. We are beginning to see that the 'old boys club' is not the way it used to be. And many of the old boys will agree that it shouldn't be that way. That represents a major step.

"Areas do exist where I think women physicians have a way to go. Indications are that women in academic medicine have a pathway to go which seems a bit different and more difficult than their male peers, and there are fewer there. Obviously,

Ardis D. Hoven, MD

we have not come to any equality in that area.

"Many people have influenced me in my career. While training in North Carolina, I was associated with some incredibly bright physicians, one of whom was Dr Janet Fisher. A true role model . . . bright, talented, had a huge family, married to a physician . . . she just did it all. But at the same time, she could sit at the bedside, or practically walk into the room and diagnose the patient. It was unbelievable that someone could be that good, that smart. But she listened, and that was the key."

Dr Hoven also listens. And she observes, studies, and approves of the traditions of KMA. "A successful year to me will be to *continue* the KMA leadership in a way that enables us to have a greater say in what happens in our profession, to persevere as we work through problems, and to *carry on* the amazing job of accessing the General Assembly. To carry on and be sure that we advance a step farther and that we do it with continuing dignity and in a way that uplifts medicine in the state of Kentucky."

Major Focus for the Year

During her year of leadership, Dr Hoven's main focus will be on health reform. "It is imperative that we stay prepared to deal with the ever shifting health systems reform, both at the state level and our interaction at the national level. This must be our number one item. We cannot let it hope to gain a life of its own without our having input," says Dr Hoven.

The governor's attempt at reform, the Clinton administration's ever-changing reform plan, and all of the variables are leaving many physicians in a quagmire of confusion. Policies developed at the KMA and AMA House of Delegates and the AMA Health Access America plan could be used as templates against which to compare proposals, but Dr Hoven wants to emphasize that it will take a broad-based knowledge. Physicians must be disciplined, realistic, and effective in responding to the issues.

"Many of our peers are going to find themselves at a disadvantage when all of this is done because they haven't kept up with the evolution of how we got from point A to point Z," affirms Dr Hoven. "It's a learning process and until we understand alternative forms of health care delivery, alternative financing, and the many variables in how medicine can be practiced, and are willing to accept them as alternatives, we are not going to understand what is coming from the national level, or potentially the local level. We must have basic, sound working knowledge. Once we have that, the same principles can be applied and used in comparing plans and organizational structures.

"Physicians are no longer being frozen out of the political process, particularly at the national level. The administration realized they were waffling around without a set of oars without our being included. I want to see this be even more apparent at the state level. It seems our state's elected officials still feel that we're not necessary to the decision-making process. Or, if we are allowed in, it's just as a courtesy. This offends me, because I don't know anyone in the General Assembly other than Drs Bob DeWeese and Nick Kafoglis who have a clue as to how to practice medicine."

The Clinton Plan

This President's year begins with some trepidation. The Clinton proposal is on the horizon, and what it will bring, no one yet knows. "You don't know who the enemy is until you see them," paraphrases Dr Hoven. "Under the Clinton plan as it now stands, the average physician will probably practice medicine in much the same way as in the past. We've been told there should be less paper, less hassle. Perhaps in time there will be some relief from tort reform and liability reform. It will be in our favor if we can get the anti-trust relief needed to govern our own in a more definitive way and to negotiate with one another. Another positive will be insurance coverage for more people."

While admitting that no plan is perfect, Dr Hoven feels that if patient choice and physicians' ability to take care of patients is protected, physicians should be okay.

KMA is entering the reform debate with a firm grounding in reality, with a great deal of wisdom and expertise, and as a worthy advocate for medicine and for patients. The Association will have communication and response strategies in place when the Clinton Plan is finally unveiled. Dr Hoven assures the membership, "We will extend every effort to ensure that membership understands the components of the plans and will help work through ways to resolve problems, to reconcile issues that perhaps were not dealt with ahead of time."

The Political Connection

Comforted greatly by the caliber and expertise of KMA's Frankfort constituency, Dr Hoven is lavish with her praise. "Our lobbyists are absolutely phenomenal. They have at their fingertips not only the experience, but the knowledge to teach the rest of us how to conduct ourselves in the political arena. Without our very bright, very knowledgeable, very astute lobbyists, we would not have achieved what we have. We owe them a great deal. They take the least of us with no experience and make us look reasonably intelligent in front of groups that are sometimes adversarial. That's a tribute to them.

"I'm finding physicians who



Proudly sharing in Dr Ardis Dee Hoven's inauguration as the Kentucky Medical Association's first woman President were her mother Dorothy Hoven, niece Toni Buck, and sister Vicki Hoven.

previously did not feel a need to become involved politically, now becoming truly concerned about the political process and realizing they have to be involved, have to integrate what they know with the legislative body and the political system. We must encourage this. It is important that we be involved in electing local officials, as well as those we send to Washington. And if so inclined, physicians or their spouses should run for election. Politics is difficult, and in the area of medical politics, we've let others go past us. You really have to have a vision, to be driven to accomplish things. It's not done for glory, nor for pay. It is done because of a desire to see the issues resolved."

Patient Advocacy & Physician Image

Dr Hoven wants to assure that true meaning stays in the words "health *care*." The health *systems* may be reformed, but *care* is and always has been the motivation for those who entered medicine for the purpose of serving, who stand united with their patients against the forces of sickness.

She is convicted and determined on two key goals she firmly espouses. "Most of my colleagues recognize that I'm a patient advocate. I firmly believe that patient advocacy has to be at the bottom of the pyramid in terms of what we achieve as physicians in the state. If we do not apply the patient advocacy rule to everything we do, we will not have achieved anything for ourselves as physicians and providers of care, nor for the individuals in the Commonwealth of Kentucky.

"Enhancing the physician's image is of utmost importance to me. Much of what we are enduring right now results from our feeling of vulnerability. We, the caregivers, the physicians who have been taking care of people the best way we know how, have been accused of being the villains. We are not the villains. There are problems within our ranks, those in it only for money and so on, and I have trouble coping with this. But I'm speaking of *real physicians*, people who really love practicing medicine, providing *care*. Many wonderful physicians are dedicating hours of time, free care, contributing to community events, community services, and no one notices. The time has come to intensely buff and polish our own image.

"I want to see physicians not have to deal with what I call 'inflammatory confrontation' — from the perspective of the press, the General Assembly, everywhere we go. Again, we are back to the buffing and polishing of our image and our role as leaders, not only in medicine, but our role as community leaders. I feel very strongly about this and about patient advocacy. Somehow, we must keep our own feet to the fire when we're looking at all issues and apply the patient advocacy rule. Now, I've been shot down about this before. People say, 'Well, this is a cat and dog world — we've got to be out there fighting.' I don't believe that."

Dr Hoven personally commits many hours to community service. She is the first woman to ever serve on the Board of Trustees for Kentucky Christian College and will go on their executive committee next year. She just stepped down as chair of the Fayette County Board of Health, and devotes a great deal of time as a member of the Governor's AIDS Policy Advisory Council.

Ardis D. Hoven, MD

Introduction to Medical Politics

Physicians are familiar with the clarion call from their chosen leaders to "get involved." Dr Hoven, who marches to a fast drummer, heeded that call long ago, without thought to where it was leading.

"I was put on site immediately when I first came to Kentucky and joined the Lexington Clinic, which pays county and KMA membership dues for its associates. After attending the appropriate meetings and serving on the appropriate committees, I eventually found myself as a Delegate to the KMA. Concurrently, HIV disease really became an issue, and I was chairing the Committee on Community and Rural Health under whose umbrella the HIV problems fell. Dr Nelson Rue took me to the Legislative Research Commission to testify, and that was the beginning — when I really perceived how medicine, how being a physician, a caregiver, had much to do with what happens on the political side. I thought they were separate entities, that the two never met face-to-face. I began to realize how they could be integrated and how important it was that people knowing what they were talking about medically were integrating the information into the system. So most of my initial leadership skills were in the area of HIV policy-making."

A goal-setter, Dr Hoven had not entertained the thought that President of the Kentucky Medical Association should be on her list. The encouragement of others who recognized her leadership abilities propelled her into the presidency. "From very early I had reinforcing help from people who are now past presidents or past board chairs. Nelson Rue . . . he clearly, clearly knew where he was directing me; Dick Hench . . . urged me from very early on to be involved; Preston Nunnelley . . . Preston and I were classmates in medical school — he's always been a few steps ahead of me, but we've sort of pedaled along the same pathway; Russ Travis has been a very strong supporter. They taught me to deal with situations. They encouraged me. One day it seems I woke up and realized 'I'm here, isn't this interesting. Guess I best get on with it now, because I either quit or I move on.' "

KMA Membership

There is no better way to accomplish goals than through the offices and activities of the Kentucky Medical Association, its component county medical societies, and the federation of the American Medical Association. Fragmentation of the profession and splinter groups detracting from the issues at hand is of major concern. Physicians must speak with a unified voice, they must work together, they cannot practice in splendid isolation any more.

Dr Hoven expressed it this way. "All physicians must come into this century. Otherwise, they are going to be left out of the loop, and they are not going to be in the loop unless they join organized medicine. The practice of medicine is evolving and it isn't going to look the same in 10 years. If they want a say in the process, they need to be saying it now. This also applies to academicians. They are no longer protected by the ivory tower.

"Taking a leadership role in organized medicine is extremely important. If we don't take control someone else will. We have the intellect, the energy, and the compassion and knowledge to impact on the future of the delivery of health care at the state and national levels in a way that may never be available again. We must have strong leadership in position to ensure that government doesn't interfere. We need to be able to work in tandem with government, and one of my greatest concerns is that we enable ourselves to be in that position. Bill Monnig, Russell Travis, and those preceding them have striven desperately to achieve this position, and we must keep up the work."

HIV and Infectious Diseases

Dr Hoven's destiny as a physician was kindled by her knack for microbiology. "I could remember the names of these unusual organisms, what they did, how they acted. It was so intriguing to me. So, I guess you could say a natural pathway led me into infectious diseases."

Infectious disease patients are most fortunate that Dr Hoven chose this specialty. She is intense about her life's work and has been at the forefront in establishing AIDS policy for KMA and physicians throughout the state. And she plans a special emphasis on HIV/AIDS education during her leadership. "One of my issues all along has been to see what we as physicians can do to impact the education of teenagers and young adults. Now, I realize this is trodding somewhat into the educational arena and bringing issues to the table which some people feel are controversial, ie, sex education. With my background in infectious diseases and HIV care, I'm dismayed by the number of young adults who acquired their disease in their mid- to late-teens and are coming into my office with HIV disease or AIDS. Many contracted it heterosexually, and it is apparent that no matter what our religious background is, no matter what our attitudes are about sexual activities or promiscuity, we must realize that if having multiple sex partners can give you AIDS, then *this behavior must stop.*

"We need not be afraid to confront this issue. We should look at it purely from the scientific, epidemiological information presented to us. We must impact

upon this information and its distribution to children, to teenagers, to their parents — through the educational system, community efforts, and our physicians' offices. AIDS education is desperately needed in our communities, and I feel that the responsible physicians of this state must address this issue."

A Personal Glimpse

A native of Cincinnati, Ohio, Dr Hoven considers herself an adopted Lexingtonian. "Lexington has been home for me since I was 7, except during the time I did postgraduate training at the University of North Carolina-Chapel Hill. My undergraduate and medical degrees were earned at the University of Kentucky, and I'm very proud of the quality of education I received at UK. I entered the very competitive medicine program at the University of North Carolina-Chapel Hill, intending to stay for 1 year and stayed 5. It was difficult deciding whether to stay in academic medicine or enter private practice. When I couldn't wait to leave the research lab to go to clinics, I realized I wasn't meant to be a bench researcher, that in fact I was a bedside physician. That was the best decision I ever made. Someone referred to me one time, however, as an academician without papers. I do a lot of teaching and my specialty lends itself to that, but clinical medicine for me remains a very important part of my life."

Dr Hoven enjoys life and is diverse in her pursuit of relaxation. "I enjoy traveling. I think of two vacations — one is restful, one is an adventure . . . and I like adventures. Although, there's not been much time for adventures lately. The seashore to me is the most wonderful place — it's very healing. It's a necessity for me to get to the beach a couple of times a year. I enjoy my home, love to entertain, to sit and talk with people. Reading, needlepoint, and being outdoors are also favorite pastimes."

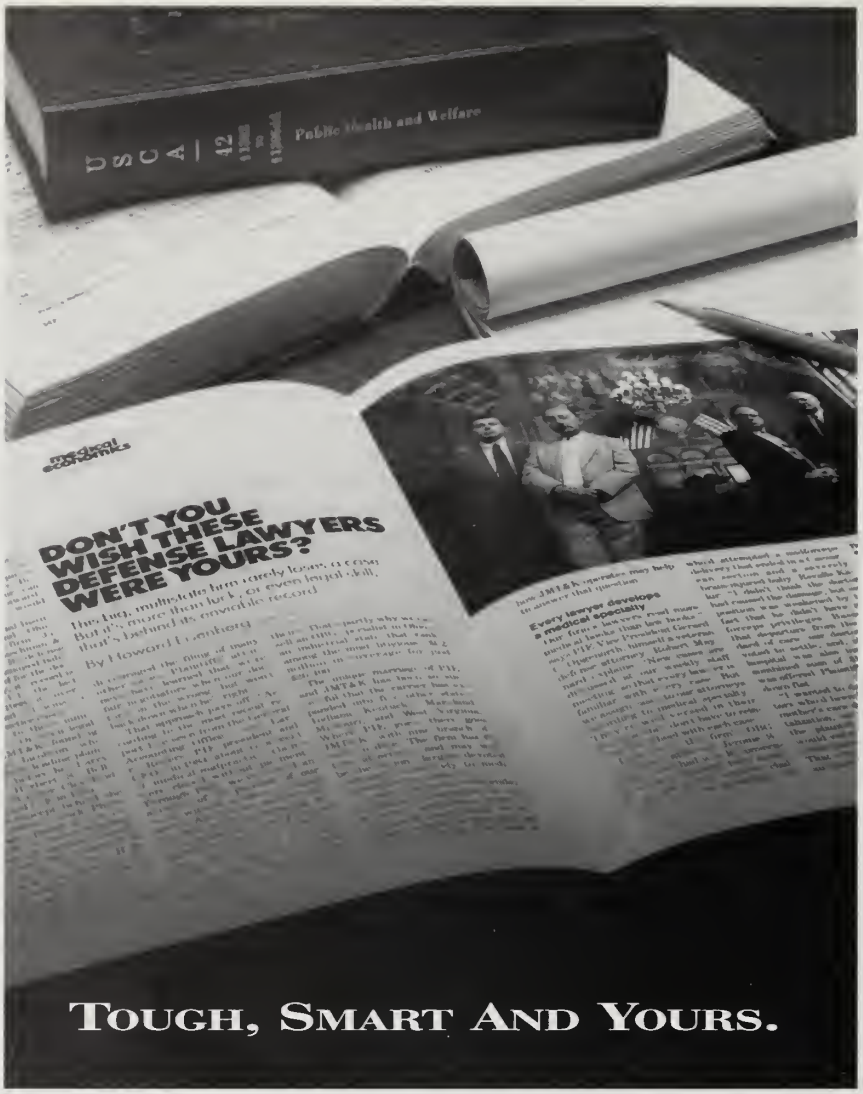
A super achiever with many activities vying for her time, Dr Hoven divulges her philosophy for avoiding stress. "Each day I have a set of things I must achieve, and I prioritize. Something rolls onto my desk, I almost automatically roll it into a priority list. This enables me to accomplish most efficiently what must be done in the shortest period of time. I'm not an athletic person, so I don't play golf, jog, or play tennis. Simply sitting and relaxing for 15 minutes revitalizes me. If something goes amuck, I confront it, deal with it, and dispense with it. I don't take things personally — carrying unnecessary baggage around interferes with my thought process. When confronting a problem, I attempt to resolve it, or realize I can't resolve it, and put it in its proper place to get on with whatever else needs to be done. I've acquired an uncanny ability to park things off to the side, to compartmentalize things, until an appropriate time to deal with them. For some, that might not be healthy, but for me it's worked very well."

The Presidency

In awe of the caliber and dedication of the officers and Board of Trustees who have preceded her and with whom she currently serves, Dr Hoven is not seeking special recognition for her presidency — she just wants to be another strong link in the chain. "The track record of my predecessors is so good, so thorough, so deliberate, and so clearly one of strong leadership, that I want to be able to walk away from my year having lived up to the tradition of the leadership of the Kentucky Medical Association. Leaders should be role models, they should share their leadership abilities, and if I can leave a trace of my philosophy on the table for others to pick up on, I will feel the year has been a success."

When asked how she would like to be remembered as President of KMA, her voice softened and one could not question the authenticity of her words. "As a kind person. As a strong leader, but one willing to listen and bend as need be to the demands of whatever the situation might be. Someone who brought a quiet, gentle strength to a period of time which was noisy and traumatic."

—Sue Tharp
Managing Editor



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Newborn Immunizations

TO THE EDITOR: Outstanding voluntary collaboration has led to good levels of coverage for Kentucky's newborns in the Universal Infant Hepatitis B Immunization Program. The program started in September 1992. By the first quarter of 1993, 80% of the estimated number of newborns had received their first dose of vaccine in the hospital. In the second quarter of 1993, the percentage exceeded 83%. To our knowledge, no other state has matched Kentucky's rapid achievement in coverage.

We attribute these results to the strong orientation toward preventive services on the part of Kentucky's physicians and hospitals. We also acknowledge how useful it was to have input in the planning of the program from members of KMA's Committee on Community and Rural Health and from a number of other interested physicians. We wish to express our appreciation for the excellent collaboration provided.

Kentucky Department for Health Services
Rice C. Leach, MD
Commissioner
Reginald Finger, MD, MPH
Director, Division of Epidemiology
Clarkson T. Palmer, MD, MPH
Manager, Communicable Disease Branch

"Kentucky Care" Plan

TO THE EDITOR: The discussion about health reform has revealed that the people who are fashioning this reform have little to no knowledge of the actual organization of delivery of medical care outside of large university hospitals.

It is possible to envision a variety of systems for providing basic medical services without resorting to extra taxation or elaborate insurance plans.

My proposal involves expanding the present "Kentucky Care" plan administered by the KMA. This program would be combined with the present system of local health departments presently operated by the state, under the administration of the county medical societies. Using local resources, donated funds and donated physician services, as well as through the hiring of nurse practitioners and nurse-midwives, basic medical services could be provided very inexpensively and efficiently through a system of clinics that would be planned at the county level. The goal would be to provide practical and inexpensive services, for instance, office visit and medication for about $10. Hospitalization could be provided by the re-establishment of ward care facilities to provide basic hospital services at low cost.

Why should physicians do this? It is their obligation to society to do so. Further, it is the only way to avoid the purgatory of socialized medicine.

By extending this line of reasoning it is possible to envision four tiers of care:

— The first tier would be an outpatient level of care administered by the county medical societies using largely their own resources as well as the resources of the county medical boards. This would be very basic medical care and medical services available to everyone in the state of Kentucky.
— The next level would be the community hospital which would be obligated to provide a certain amount of ward charity care and hospitalizations for their local communities.
— Two other tiers of service involving more elaborate urban hospitals and a third tier of purely specialty services would also be obligated to provide a certain level of charity services. Admission to one level would require unsuccessful treatment at the preceeding level.

The cornerstone of this new system has to be that the people who are able to pay should be expected to pay. It should only be the truly needy who can obtain services gratis. In return for this, the state must accept the obligation to provide substantial relief from malpractice for participants, since such a system will not be able to afford to pay large sums of money to malpractice attorneys. A system which depends on the generosity of physicians who after all will be treating their neighbors and in certain cases their friends, as well as their sense of fair play and charity, will provide much more for more people than a system which is administered by the state in the form of the present Medicaid plan. If such a system was successful it might lead to a situation where we might abolish Medicaid completely and fold that system into the system I am proposing.

F. Andrew Morfesis, MD
The Daniel Boone Clinic
Harlan, KY 40831



Board of Trustees

The KMA Board of Trustees held its fifth meeting of the Association year on August 11-12, 1993, at the Oxmoor Steeplechase Clubhouse in Louisville. Reports were given by the President; Secretary-Treasurer; President, KMA Alliance; Senior Delegate to AMA; and Chairman, Committee on State Legislative Activities. In addition, the Board heard presentations from the Board Chairman of the Kentucky Medical Insurance Company; President of the Board of Medical Licensure; Dean, University of Kentucky College of Medicine; and the Deputy Commissioner for Health Services.

An update was given on the status of health care reform in Kentucky; and the Board reiterated its support of the use of the Legal Trust Fund to challenge the constitutionality of HB 1, a provider tax bill, recently passed by the Kentucky General Assembly in special session to fund health care reform.

The Board members approved a stock purchase program for Board members and staff of Kentucky Medical; heard details of the merger of Kentucky Blue Cross and Blue Shield with its counterpart in Indiana;



President William B. Monnig, MD, addresses the Board as President-Elect Ardis D. Hoven, MD, looks on.



August Meeting



Board Chairman Russell L. Travis, MD, listens attentively to the comments of Charles J. Cronin, IV, KMA's legal counsel.

and reappointed all current *Journal* Editors.

In other action, the Board authorized a $10 voluntary assessment for the Legal Trust Fund to be included with the 1994 dues billing; authorized the addition of the Spencer County Medical Society to the Tri-County Medical Society; and reappointed the KEMPAC Board of Directors.

The Board reviewed its Ad Hoc Committee reports, as well as each final committee report to be submitted to the 1993 House of Delegates. Several Resolutions were authorized for submission to the House. A listing of actions taken to implement the directives of the 1992 House of Delegates was distributed, and it was noted that the same information would be sent to every Delegate as an addendum to the 1993 Board Chairman's Report. It was agreed to invite Alternate Trustees to attend the first meeting of the Board to be held during the Annual Meeting on Sunday, September 26.

The next meeting of the Board was scheduled for Sunday, September 26, 1993. KMA

Focus on Women in Medicine

Baretta R. Casey, MD

"Women in Charge" is the theme of the 1993 Women in Medicine Month campaign, established to bring attention to the growth and achievements of women physicians/medical students and to increase Federation membership among this important group.

The number of women physicians continues to increase. Data from KMA and AMA reveals:

— There were more than four times as many women physicians in 1990 as in 1970 and, as of the end of 1992, women physicians represent more than 18% of all US physicians. In Kentucky, 19% of all physicians are women. It is projected that by the year 2010, 30% of physicians will be women.

— The number of women medical students continues to increase. They now comprise 40% of all medical students, compared to only 9% in 1970.

— Primary care specialties comprise the largest number of women. Women are three times as likely as men to be pediatricians and less than half as likely to be in surgery.

— Almost 26,000 female resident physicians (30% of all residents) were on duty as of September 1991. In Kentucky, 280 resident physicians are female, representing 27% of the resident population.

— More than one-third of women residents were training in internal medicine or pediatrics, nationally. Another 26% were in obstetrics/gynecology, family practice, or psychiatry. Only 6% were in surgical specialties.

— The largest number and percent increase of women physicians are in office-based practice, 51% of women compared to 61% of men. Female physicians are twice as likely to be employees rather than self-employed.

— Proportionately, the number of women physicians joining medical school faculties has been consistently higher than that of men.

— The greatest percentage of women physicians are between ages 35-44 (37%).

— Along with the increase in the number of women in medicine, the number of women AMA members more than doubled between 1980 and 1991. However, membership market share continues to be lower than for men. Nationally, only 28% of female physicians are members of the AMA, while 42% of male physicians are AMA members. Kentucky statistics on AMA membership are somewhat higher: 42% of female physicians in Kentucky are AMA members, compared to 49% of male physicians.

— Membership at the state level is also higher, as 58% of all female physicians belong to KMA (64% of female practicing physicians and 34% of resident physicians.)

While the number of women physicians in leadership has increased in recent years, there are still relatively few women at the top of their medical societies. But, this is changing, as evidenced in Kentucky, as more women are at the forefront of policy-making in their local, state, and medical speciality societies, as well as the sections on medical students, resident physicians, and young physicians.

The AMA Women in Medicine Advisory Panel has been actively involved in working for women's health issues — getting family planning benefits added to the Health Access America minimum benefits proposal and addressing issues such as family violence, mammography screening, estrogen replacement, and breast implants.

As part of the national Women in Medicine month, we recognize the dedication of our women colleagues — not as token members, but as full partners in the practice of medicine. Our women members do not sit idle. They are practicing physicians sharing responsibilities for numerous committees and programs. We take this opportunity to salute their dedication and commitment to quality medical care.

Along those lines, we think it is appropriate to recognize and congratulate Ardis Hoven, MD, as the first woman President of the Kentucky Medical Association in its 143 years of existence. The first time I met Dr Hoven, she was debating the issue of mandatory testing of physicians for HIV. I was very impressed by her tenacious manner as she repeatedly upheld that physicians were professionals who had taken the oath to "first do no harm." By this statement, she was telling us that we (physicians) must be responsible for ourselves and, if we thought we were at risk of obtaining AIDS, we should voluntarily be tested.

Since that time, Dr Hoven has continued to be a role model for all physicians, especially for female physicians. She is a portrait of a physician who cares about her patients, her profession, and her colleagues. Gender has never posed a problem for Dr Hoven as she has shown her female colleagues that the road to leadership positions in organized medicine are open to any physician who has the leadership skills, knowledge of organized medicine, and dedication to the job.

Dr Casey, a third-year family practice resident at Trover Clinic, Madisonville, has recently been appointed to serve on the AMA Women in Medicine Advisory Panel. She currently is President of the KMA Resident Physicians Section, is Chairperson for the KMA Subcommittee on Domestic Violence, and is active at the state and national levels of the American Academy of Family Physicians.

PEOPLE

University of Kentucky College of Medicine Dean **Emery Wilson, MD,** was elected Chairman-Elect of the Governing Council of the AMA Section on Medical Schools at the 1993 AMA Annual Meeting. He will take office as Chairman of the Section at the 1994 Annual Meeting.

Beverly M. Gaines, MD, is currently serving as secretary and **Joseph E. Kutz, MD,** is immediate past chairman of the executive committee of the Leadership Louisville Foundation.

J. Thomas Badgett, MD, Department of Pediatrics, University of Louisville School of Medicine, was one of 31 health care experts nationwide chosen to participate in the third annual US Public Health Service Primary Care Policy Fellowship in Washington, DC.

Participants, who included physicians, nurses, dentists, pharmacists and others, discussed health care issues with Hillary Rodham Clinton's Health Care Reform Task Group and with Secretary of Health and Human Services Donna Shalala.

Additionally, they spent time on Capitol Hill learning the legislative processes involved in health care policy. The program was established 3 years ago when it was determined that not enough people are informed on primary health care issues.

"Most universities are scrambling to put more emphasis on primary care training," said Dr Badgett, who was nominated by the American Academy of Pediatrics.

UPDATES

HIV/HBV Draft Regulation

The Kentucky Board of Medical Licensure has published a draft regulation on HIV/HBV in response to Public Law 102-141 passed by Congress in 1991 that requires all state public health officials to ensure that the Centers for Disease Control (CDC) recommendations for preventing the spread of HIV and/or HBV during the performance of significant risk procedures would be followed.

The 1991 CDC recommendations were designed to further reduce the already remote possibility that a health care worker could infect a patient during the course of clinical practice. The recommendations included: that health care workers should adhere to universal precautions; that there was no basis for restricting the practice of health care workers infected with HIV or HBV who were not performing significant risk procedures; that medical, dental, and surgical organizations should identify significant risk procedures; that health care workers who perform those procedures should know their HIV antibody status; that health care workers infected should not perform significant risk procedures unless they sought counsel from an expert review panel; and finally that there was no need for mandatory testing of health care workers.

The passage of Public Law 102-141 added a mandate to a series of recommendations that had been voluntary. Congress established a deadline of October 28, 1993, for all states to have regulations in place to comply with the federal mandate.

The Community and Rural Health Committee developed a policy for preventing the spread of the disease from physicians to patients during significant risk procedures. The policy was approved by the KMA Board of Trustees at its December meeting, and was forwarded to the Kentucky Board of Medical Licensure for consideration. The regulation drafted by the Licensure Board is as follows:

Section 1. Definitions. (1) "HIV" means the human immunodeficiency virus.

(2) "HBV" means the hepatitis B virus.

(3) "Universal precautions" means the appropriate use of hand and skin washing, protective barriers, care in the use of and disposal of needles and other sharp instruments, and those other techniques recommended in update: universal precautions for prevention of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health care settings, MMWR 37:377, 1988, hereby incorporated by reference. A copy may be inspected or copied at the board's office during business hours.

Section 2. HIV or HBV Serostatus Determination. A physician who is HIV or HBV seropositive (and "e" antigen positive) and who performs patient care procedures which pose a significant risk of transmission of HIV or HBV to patients may seek counsel from the Kentucky Board of Medical Licensure.

Section 3. Review and Monitoring of HIV or HBV Positive Physicians. The Kentucky Board of Medical Licensure shall be empowered to convene a review panel including, but not limited to, the HIV or HBV positive physician's primary care physician, a clinical infectious disease specialist and an epidemiologist representing the Kentucky Department of Health Services. The review panel shall have the following functions:

(1) Monitoring of the HIV or HBV positive physician's adherence to universal precautions, clinical competency and any practice limitations or restrictions established by the review panel to monitor compliance with universal precautions.

(2) Periodically evaluate the effects of the disease on the physician's competency.

Section 4. Disciplinary Action. Any physician who does not comply with the requirements of this

administrative regulation or the limitations and restrictions established by the review panel, pursuant to regulation, shall be subject to disciplinary action by the Kentucky Board of Medical Licensure as set forth in KRS 311.595.

Section 5. Confidentiality. Information obtained by the Kentucky Board of Medical Licensure pursuant to this regulation is personal in nature as set forth in KRS 61.878(1)(a) and is excluded from the application of KRS 61.870 to 61.884.

The Legislative Administrative Regulations Review Committee approved the regulation on September 3, 1993, so the regulation is now final as written.

Requirements for Political Contributions

The Kentucky Registry of Election Finance has asked the KMA's assistance in informing our members that giving of *corporate* contributions, either directly or indirectly, to any candidate for public office is prohibited. The *acceptance* of *any* corporate contribution by any candidate for public office is also prohibited.

In addition, contributions by public service corporations to candidates, as well as receiving such contribution by the candidate from the public service corporation are illegal.

No-Scalpel Vasectomy

The University of Louisville reports that a new surgical technique performed by a U of L urologist may help ease the fear of the surgeon's knife that keeps many men from undergoing vasectomies.

Arnold M. Belker, MD, uses a less-invasive technique called "no-scalpel vasectomy," in which he operates through a tiny puncture instead of a large incision.

The outpatient surgery takes less than half an hour, is performed under local anesthetic, and requires no stitches. Dr Belker says the procedure produces fewer complications, less bleeding, and usually less pain than conventional vasectomies.

Ear Thermometers

Taking temperatures with tympanic, or ear, thermometers is easier, quicker, and more pleasant than other methods. But a University of Louisville researcher thinks the ear thermometers may not be the best for taking temperatures.

Eddie A. Hooker, MD, an assistant professor of emergency medicine, studied 39 children and found that the ear thermometer failed to detect high temperatures in one-third of the children who had fever. A study of adults yielded similar results, he says.

According to Dr Hooker, the most accurate tool for taking a temperature still is the rectal thermometer.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Boyd

Dino D'Aloisio, MD — FP
3723 Pinetree Ct, Ashland 41102
1980, U of Toronto

David K. Goebel, MD — IM
706 23rd St, Ashland 41101
1986, U of Kentucky

Calloway

Mehdi Ahmadi, MD — ONC
300 S 8th St #376, Murray 42071
1975, U of Tehran

Floyd

Everett J. Horn, MD — OBG
PO Box 608, Prestonsburg 41653
1989, U of Kentucky

Franklin

Karen R. Scott, MD — OBG
3025 Versailles Rd, Frankfort 40601
1985, George Washington U

Graves

Carmine B. Petracca, MD — OBG
220 W Walnut St, Mayfield 42066
1988, St. George's U

Hopkins

Satish J. Shah, MD — R
900 Hospital Dr, Madisonville 42431
1979, B J Medical College, India

Hardin

David E. Bertler, MD — D
2020 Oriole Dr, Elizabethtown 42702
1985, Uniformed Services U, Bethesda

Jefferson

Alberto J. Carrillo, — PHD
PO Box 35070, Louisville 40232

Royce D. Coleman, MD — EM
2756 Campion Rd, Floyds Knobs, IN 47119
1984, U of Louisville

Gregory K. Collins, MD — FP
2819 Newburg Rd, Louisville 40205
1976, U of Louisville

David R. Cundiff, MD — PM
400 E Gray, Louisville 40202
1980, U of Pennsylvania

Marietta Enriquez, MD — PD
10804 Dixie Hwy, Louisville 40272
1967, Manila Central U

Lisa R. Kirsch, MD — C
1902 Bainbridge Row Dr, Louisville 40207
1986, SUNY, Syracuse

Kay L. Miller, MD — IM
8201 Copper Creek Dr, Louisville 40222
1983, State U of South Dakota

Kamala S. Mokshagundam, MD — IM
7620 Greenlawn Rd, Louisville 40241

1986, Topiwala Med Col, India
Walter L. Olson, Jr, MD — N
UL-Dept of Neurology, Louisville 40292
1973, Medical Col of Ohio
Hugo L. Perez, MD — OBG
6208 Preston Hwy, Louisville 40219
1987, U Central, Puerto Rico
Jack M. Perlman, MD — GP
8134 Montero Dr, Prospect 40059
1960, U of Wisconsin
Trudi L. Rash, MD — PD
7500 White Post Way, Louisville 40220
1989, Marshall U
Andrew T. Reiners, MD — AN
6841 Steep Run Rd, Louisville 40241
1983, Indiana U
Traci L. Wagner, MD — PD
2225 Wadsworth Ave, Louisville 40205
1989, U of Miami
Lois C. Weixler, DO — GP
9613 Fairground Rd, Louisville 40291
1989, Col of Osteopathic Med, Des Moines

McCracken

Bernie L. Brunson, MD — S
9 Park Pl, Paducah 42003
1988, U of Louisville

Perry

Uday T. R. Shankar, MD — IM
200 Medical Ctr Dr, #2B, Hazard 41701
1982, Bangalore Med Col, India

Wayne

Edward Joseph, MD — U
207 Homestead Ln, Monticello 42633
1966, Boston U

In-Training

Jefferson

Kevin J. Breen, MD — P
Christine A. Cappelle, MD — PD
Kevin W. Eggerman, MD — P
Sean M. Maguire, MD — OTO
David M. Passafiume, MD — AN
Anthony R. Serlinger, MD — AN
Ruth Ann Serneels, MD — PD
James M. Watkins, MD — S

DEATHS

Robert C. Clear, MD
Bellevue
1924-1993

Robert C. Clear, MD, a family practitioner, died August 1, 1993. Dr Clear graduated from the University of Cincinnati College of Medicine in 1955 and was an active member of KMA.

John C. Cheshire, Jr, MD
Frankfort
1942-1993

John C. Cheshire, Jr, MD, an obstetrician and gynecologist, died August 3, 1993. A 1969 graduate of the University of Kentucky College of Medicine, Dr Cheshire was an active member of KMA.

Donald B. Thurber, MD
Frankfort
1911-1993

Donald B. Thurber, MD, a retired public health physician, died August 3, 1993. Dr Thurber was the former director of immunization for the State Department of Health, heading statewide oral polio vaccine distributions in the 1960s. He graduated from the University of Louisville School of Medicine in 1936 and was a life member of KMA.

Correction

In the September 1993 obituaries, **Edward M. Haick, MD,** was incorrectly identified as a graduate of Northwestern University Medical School. The *Journal* has been advised that Dr Haick was a 1961 graduate of the University of Louisville School of Medicine. We deeply regret this report of incorrect information.

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AIR FORCE

From Green Persimmons To Cranky Parrots: Practice Management Axioms To Live By

Robert L. Slaton, EdD, FACMGA,
Bob Mannin, Clyde Jackson
Medical Group Management Association
104 Inverness Terrace East
Englewood, CO 80112

This folksy, storytelling type book reads easily and sprinkles information about practicing medicine throughout the pages. Ten "Axioms" divide the book in what we call sections, with suggestive titles heading the parts. Short staccato sentence parts such as "Timing is almost everything," "There are different strokes for different folks," "Look in the mirror, take a deep breath," and "You never have a problem — only an opportunity," are only four of these slogan type introductions. The authors' bias bubbles out in their consultant type language and simplistic talk. In fact, it seems the reader is the one who hires these people to straighten everything out! Nevertheless, once past this pedantic and sometimes authoritarian approach, you can appreciate many experiences and success stories through the written words. Cartoons at the beginning of each "Axiom"-section reduce the believability of the book, since the readers are usually adults and not in the mood for frivolity when something is wrong with their practices.

Interspersed with the straightforward what to do lines are many tales about what happened to someone else. Such biography and nonfiction give the book a news magazine like quality, but make for lighter reading. By the end you feel that your time was well spent, if not somewhat extended unnecessarily with tale spinning!

Ethical Health Care Reform — Person-Focused Reorganization

Ignacio Ripoll, MD

Hampton Roads Publishing Company, Inc
891 Norfolk Square
Norfolk, VA 23502
1993
$8.95

As I grabbed this thin book from my reading table and felt its skinny body of 75 pages, I conditionally categorized its contents as another health care reform article, or short discussion, about which I had heard almost daily diatribes. Several hours later I considered the time well spent, but was not any happier. Dr Ripoll is a pulmonologist, holds an academic appointment at Eastern Virginia Medical School, and has an itinerant past practicing in several foreign countries, in medical school and Veterans hospitals, and apparently in classic "private practice." What qualifies him to discuss such a complicated subject in succinct terms and language is his charge to present the health care crisis from an ethical, patient-oriented perspective.

Robert V. Stanek, a hospital administrator, prefaces the book with a wordy discussion of the hospital biased input and is not worth reading in depth. Then Dr Ripoll begins the book with about 16 pages headed as "The Problems." Obviously, having read tomes about all the problems, this short discussion is the least important part of the book. "The Solutions" takes up the rest of the book and is filled with catchy phrases like "A Treatment Plan to Heal the Health Care Industry" with its "prescriptions," and "The Civil War Within the Health Care Industry." Throughout his talk with us, the readers, Dr Ripoll inserts a moralistic fervor with his frequent use of "responsibility," "value," "mission," and many others. His remedy relies on his pleading for a religious commitment to do right, to accept the word reform verbatim. This book reads like a preacher's lecture to a congregation, threatened with sabotage from the religious right and from the agnostic left. Consumers of health care, whether clothed in overalls or pin-stripped suits, whether holding a wallet full of government money or a small white card emblazoned with multi-digit numbers, are the congregants. Sometimes we physicians are portrayed as the elders, other times as the sinners. Nevertheless, this book does focus on the moral commitment necessary to truly reform medicine. Basically Dr Ripoll is saying to us, do what we know is right, not for profit or ego or power, but for the patient's best interest. Rewards will ensue, although probably not as many and not as frequent. The book is worth reading, the price is just a few lottery tickets, and the gambling industry needs reform, and less of our money!

Stephen Z. Smith, MD
Book Review Editor

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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin, the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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D3-K005

Issued. March 1993

Bristol-Myers Squibb Company

THE PRAVACHOL® DIRECTION IN LIPID MANAGEMENT

Effective lipid management doesn't have to be tough



- Improves key lipids — significant reduction in LDL-C[1]
- Excellent safety profile
- Easy for patients — once-daily dosing, well tolerated
- Usual dose: 20 mg once daily at bedtime, with or without food

PRAVACHOL®
pravastatin sodium 20 mg tablets

PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

Bristol-Myers Squibb Company

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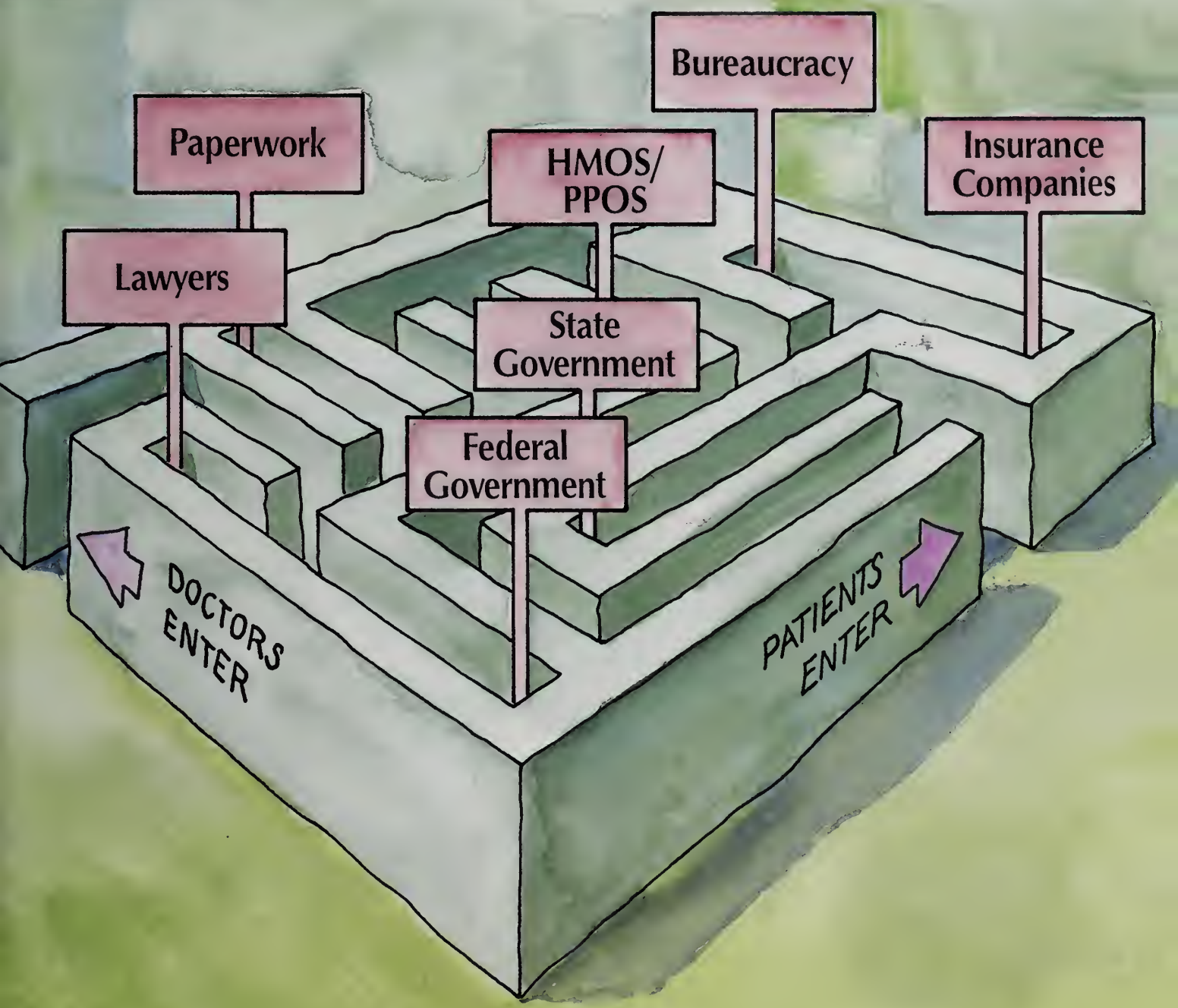
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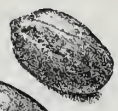
NOVEMBER 1993
VOLUME 91, NUMBER 11

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And we charge more.



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Medical liability insurance companies are more than willing to make one  of your most important decisions for you. In fact, they insist on it. The decision on whether to go  to court or settle a claim. Yet insurance company lawyers who make that decision have their company's bottom line — not your reputation — as their only concern. And a decision to settle can put your reputation at risk. Permanently. Because even if you're right as rain, you look wrong. Guilty. So our policies guarantee we don't settle  unless *you* want to settle. Which is very likely one reason we're sponsored by the Kentucky Medical Association. As well as being the leading provider of medical liability insurance in our area. For complete information, call 1-800-467-1858. The decision to call — like the decision to settle — is yours.

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Discover The Elegance Of A Hybrid



At first glance, it's the *beauty* of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its *elegance* becomes apparent—a gentle blend of softness and strength.

At first glance, it's the *enhanced performance* of Vaseretic that catches the eye. But study Vaseretic more closely, and its *elegance* becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid *blending of tolerability and power* that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

10 mg



25 mg



USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See *WARNINGS, Fetal/Neonatal Morbidity and Mortality.*

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General: Enalapril Maleate: Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide*).

Pregnancy: Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality*, below.)

Enalapril Maleate: Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide: Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5.6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General: Enalapril Maleate: Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent preexisting renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium*).

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients: Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions: Enalapril Maleate: Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide: When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings: Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia, atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported, a causal relationship to enalapril has not been established. *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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The Hospital Medical Staff Section
22nd Assembly Meeting
December 2 - 6, 1993
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HMSS representatives won't want to miss this year's AMA-HMSS Interim Assembly Meeting. They will have an opportunity to learn about and discuss with AMA's leadership and staff the details of President Clinton's health care reform proposal as well as AMA's legislative strategy.

HMSS representatives will also be presented with an overview of physician and physician/hospital organizations, including the physician hospital organization, management services organizations, the foundation and physician equity models, and the hospital-affiliated professional corporation.

Review and analysis of President Clinton's Health Care Reform Plan

President Clinton released his new health care reform plan in September. HMSS representatives in this session will hear a full review and analysis of the plan.

Physician Organizations & Hospital Organizations

Henry E Golembesky, MD, director of Integrated Health Systems Practice of American Practices Management and former chief executive officer of UniMed America, will discuss and examine, from a physician's perspective, the advantages and disadvantages of the organizational structures being created in response to federal, state, and business health care reform initiatives. He also will identify the key elements of successful physician and physician/hospital organizations.

Dr Golembesky will be joined by several physicians who currently practice in these structures. They will share their experiences and cite the challenges and opportunities for physicians. HMSS representatives will be able to ask questions of the physician panelists and together explore mechanisms to maintain physician control in the credentialing of network providers, the monitoring and assessment of patient care, and the setting of quality of care standards/outcomes.

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JOURNAL OF THE
KENTUCKY MEDICAL
ASSOCIATION

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COVER: Maintaining the continuity of the patient/physician relationship is like navigating a maze. Refer to article beginning on page 495 for suggestions on coping with patients' questions and influencing health system reform.
Cover art by Lee Wade of Louisville.

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Ardis D. Hoven, MD

Phase II

We have successfully concluded the 1993 Annual Meeting of the Kentucky Medical Association with thoughtful deliberations by the House of Delegates. As anticipated, considerable attention was given to issues related to health care reform in Kentucky and the recommendations soon to be promulgated by the Task Force. We look forward to continued activity on your behalf as we approach this next level of deliberations by the General Assembly.

For a period of time, however, we must turn our attention to the activity at the national level and to President Clinton's "American Health Security Act of 1993," which has now entered Phase II with Congress beginning its deliberations. This will be a prolonged process with numerous bills emerging from both parties with considerable attempts to provide a bipartisan approach. It has been said the American Medical Association's plan for health care reform, *Health Access America,* has served as the mother of all health care bills. Unfortunately, the Clinton administration will attempt to "de-strengthen" the unified voice of physicians by pitting one group against another in matters of reimbursement and delineation of patient responsibilities. As physicians, we must be very careful as we speak out about what we do and do not support, and make a balanced assessment of the proposals.

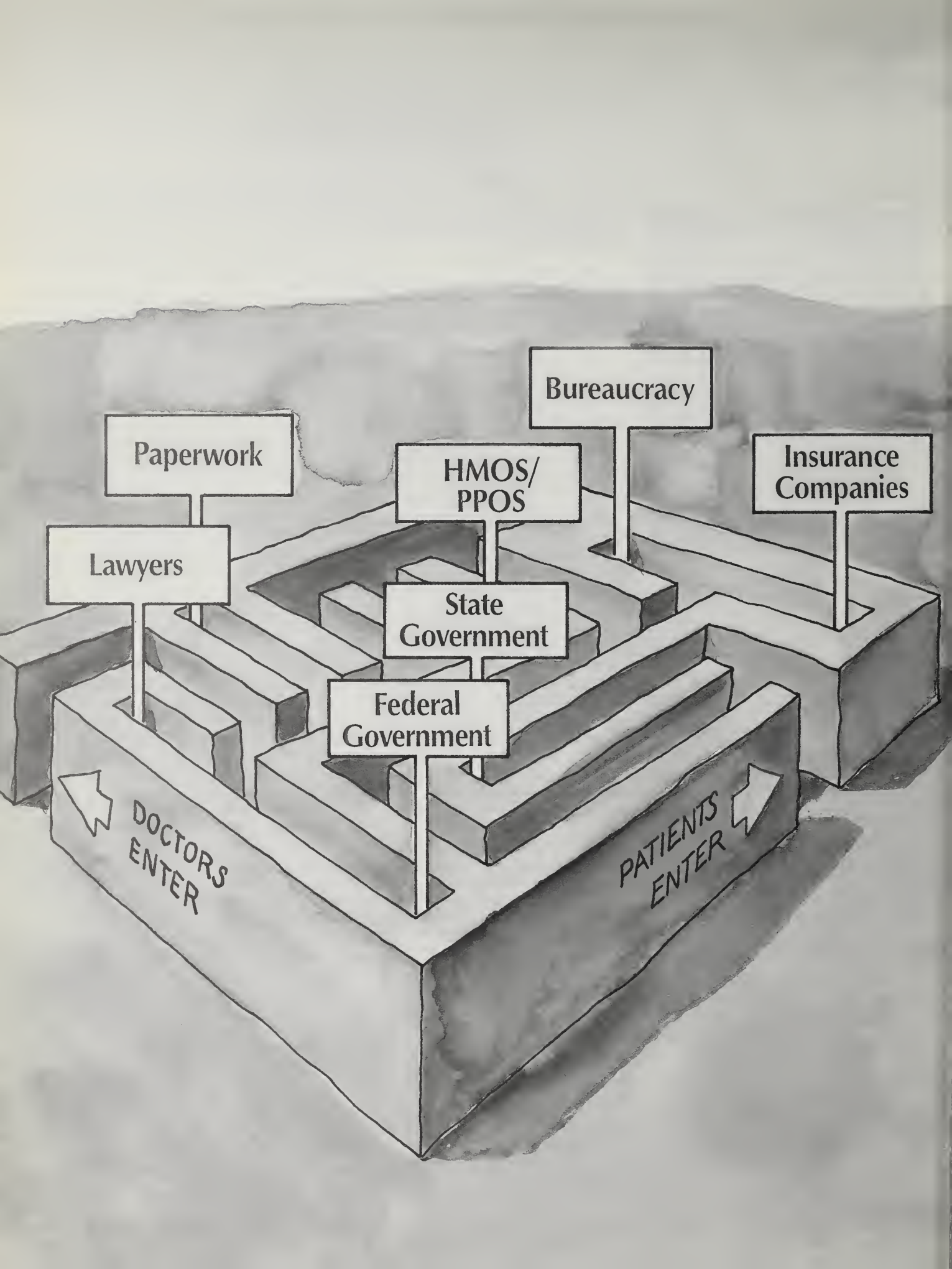
You will soon receive a very detailed document reviewing the elements of the Clinton plan and the AMA's response. I encourage you to study this carefully and be prepared to discuss it with your patients, your neighbors, your peers, and your community leaders.

Universal access to care, a good comprehensive benefit package, meaningful insurance reform, a reduction in bureaucracy and paper, and a mandate for employers to provide health insurance are considered to be key elements to addressing the problems related to the delivery of health care in this country. However, when you begin your study of the plan recognize that it will limit choices for patients and physicians, and government and its agencies will be positioned between the patient and the physician with an excess of centralized regulation and federalization of many elements of health care. The mechanism by which this endeavor will be funded is not clear, there is inadequate liability reform, and the President will propose rigid spending limits that will limit resources and not resolve the problems. The establishment of a national health board would create a uniquely powerful body with almost unlimited capabilities and responsibilities in setting budgets, determining expenditure targets, overseeing all health plans, and setting quality standards of health care.

Health care reform cannot be a spectator sport! Be knowledgeable and be involved!

Ardis D. Hoven, MD
KMA President

"Unfortunately, the Clinton administration will attempt to "de-strengthen" the unified voice of physicians by pitting one group against another in matters of reimbursement and delineation of patient responsibilities."


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Is health reform good for your patients? You need to think about these 10 questions.

1. Will they still be able to see their own doctor? Will they have to pay extra? And will the doctor and patient be free to decide how to treat an illness?
2. If the patient has a group insurance policy through their employer, will that change? Will premiums, deductibles and co-payments go up?
3. Will patients be able to choose their own type of health insurance? And can extra insurance be obtained if they want it?
4. Will anything be done to reduce and simplify all the insurance forms patients and doctors have to fill out?
5. What happens if patients change jobs, get sick or injured? Will they risk losing health insurance coverage?
6. What if someone in the patient's family has a preexisting health condition. Will they be covered?
7. Will the quality of care patients and their family receive be maintained under a new system?
8. What if the patient is retired and on a fixed income. Will Medicare coverage be affected?
9. Will costs be controlled in a way that doesn't interfere with medical care?
10. Will everybody in Kentucky have health insurance? If so, how will we pay for this?

Washington and Frankfort are proposing changes in the way health care is accessed, delivered, and financed. Urge your patients to be informed of changes that effect access to care, costs, and the patient/physician relationship. If you would like information about these and other questions being raised, call the KMA or the AMA, or write or call your elected representatives.

4 things physicians can do *now* to influence Health System Reform

Here are specific ideas on how *you* and your county medical society can take advantage of this opportunity.

1. Sponsor a mini-internship

What better way to help legislators understand physician's perspective than a behind-the scenes look at medical practice?

A mini-internship is a chance for legislators to work in physicians' footsteps. Interns accompany doctors during office visits, hospital/nursing home rounds, surgery, emergency care — even peer review and consultations.

In an ideal two-day program, each intern has four half-day placements — with an emergency room physician, a surgeon, a family practitioner and a specialist. After the internship, interns and physicians meet at a debriefing dinner to discuss their experiences. (Shorter sessions are also effective.)

How to Organize a Mini-Internship for your Legislators

- Coordinate mini-internships with KMA's government relations department. They can help prioritize which legislators to invite.
- Use a persuasive approach: Members of the Kentucky General Assembly and Congress will make critical health care decisions in the coming months. Here's a chance to witness firsthand the delivery of health care and the crucial relationship between physician and patient.
- Be as flexible as possible in scheduling. Set two or three tentative dates; find out which is best for legislators. If legislators cannot devote two days, consider a one-day mini-internship. Only half a day to spare? Try arranging a one-on-one placement with a primary care physician.

2. Get your society's message out through the local media

- *Editorial boards.* Plan a visit to make your county society's response to health care reform proposals known to the media.
 — Remind editors that physicians, as patient advocates, are eager to be part of the health system reform process.
 — Pick your physician spokesperson. Stick with one or two qualified spokespersons. You may have only one shot — use your best spokesperson.
 — Be prepared. Spokespersons should prepare an opening statement summarizing your arguments. Anticipate tough questions and rehearse responses.

- *Op-eds*. Use editorial pages to voice society's opinions on health care reform. Add personal touches. Describe patient care examples of limited access to health care. Emphasize the number one interest of physicians: quality patient care.
- *Letters to the editor*. Respond to media coverage of system reform by writing letters to the editor, especially when you disagree.

3. Plan visits with your state senator, representative, and congressional representatives

Early fall will be a prime time for county medical societies to meet with legislators. With health system reform at the top of the agenda, elected representatives will want to talk to physicians.

- Consider hosting meetings in cooperation with local AARP chapters, chamber of commerce, business groups, etc. Invite elected repesentatives, media, medical society members and the public to discuss health care reform.
- Invite members of the General Assembly and Congress to medical society forums to outline their positions and offer insights on health care reform.
- Host a "meet your state senator and representative" dinner for physicians and their spouses.

4. Form a county society legislative committee

Committee responsibilities would include:

- Assist county society's Key Contacts with local legislators.
- Study legislation/reporting to the society leadership and membership.
- Work with KMA officers/staff during regular and interim sessions of the General Assembly.
- Meet with legislators on a periodic but scheduled basis.
- Include a member of the local Alliance (Auxiliary) on the committee. Alliance members (spouses) are formidable political allies, and extremely effective in working with and contacting legislators.
- Set up local phone bank to alert physicians/spouses of important votes on legislation.

There has never been a more critical time for Kentucky medicine to make its voice heard. The health system reform decisions made in Washington and Frankfort in the months ahead will affect physicians and patients far into the next century.

This fall presents a unique window of opportunity. The release of both President Clinton's plan and Governor Jones' latest proposal will spark renewed interest in system reform among legislators, the media and the public.

Specific legislation on both the national and state scene have been introduced. Couple that with the General Assembly's reluctance to adopt Governor Jones' original plan, and the possibility that Congress may delay final enactment of national legislation to the fall of 1995. The opportunity to influence the health reform agenda becomes even more significant.

Elevated Lipoprotein (a) Blood Levels as the Single Treatable Atherosclerotic Risk Factor in Patients With Coronary Artery Disease

Harold Bays MD; Carlos A. Dujovne, MD; J. Brent Mays, PA-C

Dr Bays is Medical Director of The Lipid Center, Audubon Regional Medical Center, Louisville, KY; Dr Dujovne is Director of The Lipid and Arteriasclerosis Preventian Clinic, University of Kansas, Kansas City, KS.

An elevated blood level of lipoprotein (a) [Lp(a)] has been studied as an independent risk factor for coronary artery disease. We report a series of nine consecutive patients with clinical onset or recurrence of coronary artery disease who presented without treatable atherosclerosis risk factors, five of whom had elevated Lp (a) blood levels. Indications for measuring Lp (a) levels and usefulness of niacin therapy are reviewed.

Reduction in coronary artery disease (CAD) morbidity and mortality has been shown with correction of treatable CAD risk factors such as dyslipidemia, hypertension, cigarette smoking, and/or diabetes mellitus. Other CAD risk factors such as family history of CAD, male gender, and aging are not amenable to intervention.

Recommendations directed towards reducing the progression of atherosclerosis in patients with CAD without treatable CAD risk factors is unclear. It has been suggested, although not shown by controlled trials, that an elevated blood level of lipoprotein(a) [Lp(a)] may be an important CAD risk factor in these patients.[1,2]

We describe nine consecutively detected patients with clinical onset or recurrence of CAD who presented without treatable CAD risk factors. Their fasting blood levels of "routine" lipoproteins would not have required lipid-acting drug therapy according to 1988 National Cholesterol Education Program (NCEP) recommendations.[3] Five of these nine patients had elevated Lp(a) blood levels.

Patient Selection

Of approximately 2400 patients assessed at our clinic between the years 1986 and 1992, data was evaluated on the first nine consecutive patients who presented with onset or recurrence of CAD and no treatable CAD risk factors (including dyslipidemia, hypertension, diabetes mellitus, and/or cigarette smoking within 10 years of onset or recurrence of CAD).

Fasting total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C) and triglyceride (TG) blood levels were obtained within 1 year prior to recurrence, or 6-12 months after the clinical onset of CAD. Only those patients with CAD, absent treatable CAD risk factors, and fasting LDL-C $<$ 4.14 mmol/L (160 mg/dl), HDL-C $>$ 0.91 mmol/L (35 mg/dl), and/or TG blood levels $<$ 2.82 mmol/L (250 mg/dl) were included in this report.

Lp(a) blood levels were subsequently measured in all nine of these patients by enzyme-linked immunosorbent assay at either of two Lipid Research Center Laboratories within 3 years of the clinical onset or recurrence of CAD. No patients had been treated with lipid acting drug therapy prior to the measurement of Lp(a) or other lipoprotein blood levels.

Clinical onset of CAD was defined as a myocardial infarction or documented coronary artery disease by cardiac catherization occurring in patients without previous history of CAD.

Recurrent CAD was defined as progression of atherosclerotic lesions documented by cardiac catherization or stress thallium testing in patients with previously clinically successful coronary artery by-pass grafting.

The pertinent clinical and laboratory data are outlined in Table I.

Discussion

Epidemiologic studies suggest that over 10% of patients who develop CAD have blood TC levels below 5.17 mmol/l (200 mg/dl). Many of these

Table I. Blaad Lp(a) and Other Lipopratein Levels in Nine Patients With Clinical Onset ar Recurrent Caranary Artery Disease Withaut Treatable CAD Risk Factors (see text).

	Patient	Age/Sex (Years)	TC mmal/L (mg/dl)	LDL-C mmal/L (mg/dl)	HDL-C mmal/L (mg/dl)	TG mmal/L (mg/dl)	Lp(a)* mmol/L (mg/dl)	FH **	Time between 1st and 2nd CAD event	1st Coronary Artery Event	2nd Caranary Artery Event
Recurrent CAD	(1) RL	70/M	6.03 (233)	3.93 (152)	1.66 (64)	0.94 (83)	0.39 (15)	2	9 years	Multivessel CAD	Multivessel CAD
	(2) WL	75/M	5.51 (213)	3.93 (152)	1.09 (42)	2.41 (213)	0.85 (33)	3	13 years	Multivessel CAD	M.I.
	(3) PH	52/M	4.94 (191)	3.15 (122)	1.03 (40)	1.66 (147)	0.18 (7)	1	7 years	Multivessel CAD	Multivessel CAD
	(4) MS	69/F	4.89 (189)	2.41 (93)	1.66 (64)	1.83 (162)	0.18 (7)	?	22 years	Multivessel CAD	Angina
	(5) EY	57/F	5.38 (208)	4.09 (158)	1.11 (43)	1.50 (133)	3.31 (128)	3	4 years	Multivessel CAD	Single vessel CAD
Clinical onset of CAD	(6) MB	58/M	4.06 (157)	2.41 (93)	1.37 (53)	0.60 (53)	0.93 (36)	1	—	Multivessel CAD	
	(7) JM	50/M	5.59 (216)	3.72 (144)	1.01 (39)	1.98 (175)	1.27 (49)	2	—	M.I.	
	(8) CW	53/M	4.32 (167)	3.75 (145)	0.96 (37)	1.14 (101)	1.45 (56)	1	—	Multivessel CAD	
	(9) TS	66/M	2.79 (108)	1.50 (58)	0.96 (37)	0.75 (66)	0.41 (16)	3	—	M.I.	

* Narmal Lp(a) blaad levels are less than 0.52 mmal/L (20 mg/dl).
** Family histary (FHx) risk is coded as:
1 = First degree family member with CAD older than age 55 years ald
2 = First degree family member with CAD younger than 55 years ald
3 = Mare than ane first degree family member with CAD yaunger than 55 years ald
? Patient was an arphan and did nat knaw family history.
TC = Tatal chalesteral, LDC-C = Law density lipapratein chalesteral; HDL-C = High density lipapratein chalesteral; TG = Triglycerides, Lp(a) = Lipopratein (a)

patients have other treatable CAD risk factors such as low HDL-C and/or high TG blood levels, cigarette smoking, hypertension, and/or diabetes mellitus. However, some patients present with onset or recurrence of CAD without these treatable CAD risk factors.

An elevated Lp(a) blood level is thought to be an important CAD risk factor because of the potential increased risk of atherosclerosis and/or thrombosis.[2] Elevated Lp(a) blood levels are strongly associated with CAD, stenosis of carotid and cerebral arteries, as well as saphenous vein bypass grafts,[1,5] independent of other CAD risk factors such as cigarette smoking, hypertension, diabetes, increased LDL-C, decreased HDL-C, and/or elevated apolipoprotein A-1 and B blood levels.[4]

Individual Lp(a) blood levels remain constant throughout life,[2] are thought to be generally unaffected by diet and/or lifestyle intervention, and are in large part genetically determined. For some patients, elevated Lp(a) blood levels have been suggested as the most prevalent inherited risk factor for atherosclerosis.[6] All patients in this report found to have elevated Lp(a) blood levels had a family history of CAD (although in one patient, the family history was unknown).

Indications for measurement of Lp(a) have not been established; however, abnormally elevated blood levels have been suggested to be the best discriminator between Familial Hypercholesterolemia (FH) patients with CAD, and FH patients without CAD. In fact, elevated Lp(a) blood levels in patients with FH have been reported to be a better discriminating factor than other more established CAD risk factors such as age, sex, smoking, and all other "routine" lipid and lipoprotein blood levels.[7] Thus, measurement of Lp(a) blood levels may help determine which patients are possibly at higher risk for development of CAD, and may theoretically require more aggressive therapy.

Because levels may transiently rise after myocardial infarction,[8] blood levels of Lp(a) are best measured 2-3 months after any CAD event. A higher incidence of elevated Lp(a) blood levels

have been reported in blacks,[5] patients with a family history of CAD,[4] postmenopausal compared to premenopausal women[1] (although gender differences have not been established[4,5]), as well as in patients with renal failure treated with chronic hemodialysis, nephrotic syndrome, poorly controlled diabetes mellitus, ethanol withdrawal in alcoholic men, and possibly untreated hypothyroidism.[1,6,9]

We report another subset of patients who may benefit from measuring Lp(a) blood levels. We evaluated nine consecutive patients with clinical onset or recurrence of CAD and no other treatable CAD risk factors. Five of these nine patients were found to have elevated Lp(a) blood levels.

Although controlled clinical trials have yet to demonstrate that lowering Lp(a) blood levels reduces CAD morbidity or mortality, recent reviews site isolated case reports and small studies (not always well controlled) suggesting that interventions such as vigorous aerobic exercise, omega-3 fatty acids, gemfibrozil, postmenopausal estrogen replacement therapy, LDL-C apheresis and other agents such as anabolic steroids and ascorbic acid may help lower Lp(a) blood levels.[1] However, niacin is the only lipid-acting medication which has been shown to consistently lower Lp(a) blood levels[1] over 30%, depending upon the dose and individual patient responses.[10]

In patients with CAD and other dyslipidemias, the presence of elevated Lp(a) blood levels may prompt the use of niacin, not only because niacin has been shown to reduce Lp(a) blood levels, but also because niacin therapy has been shown to decrease atherosclerotic progression and has therefore been recommended by the National Cholesterol Education Program (NCEP) as a first line therapy for a wide spectrum of abnormal blood lipids.

In patients with CAD and no other treatable CAD risk factors found to have elevated Lp(a) blood levels, no current recommendations exist to reduce atherosclerotic progression. However, in addition to lowering Lp(a) blood levels, niacin may be indicated to improve HDL-C and TG, and to lower LDL-C blood levels beyond the 1988 treatment goals of the NCEP. This more aggressive approach may be justified due to the increase in atherosclerotic risk associated with elevated blood levels of Lp(a), and because of the onset or recurrence of CAD with "routine" lipoprotein blood levels not otherwise requiring lipid acting drug therapy.

Finally, elevated Lp(a) blood levels have been suggested to compete with plasminogen, which is a natural fibrinolytic substance.[2] Because intervention trials have shown that aspirin reduces subsequent thrombotic coronary artery events in patients with CAD, aspirin therapy may be especially important in patients with CAD *and* elevated blood levels of Lp(a) to decrease the potential increased risk of thrombosis.

Conclusion

Previous studies have suggested that elevated Lp(a) blood levels are an independent risk factor for CAD. Our report suggests that an elevated Lp(a) blood level may be an important measurable and treatable CAD risk factor in the subset of patients with clinical onset or recurrence of CAD and no other treatable CAD risk factors. Therapeutic guidelines for such patients are not available, and a reduction in CAD by lowering Lp(a) blood levels awaits confirmation by clinical trials. However, niacin therapy may be justified in these patients, not only to lower Lp(a), but to improve other lipoprotein blood levels.

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False Pregnancy: An Unusual Paraneoplastic Syndrome Associated With Bronchogenic Neoplasm

Ryland P. Byrd, MD; Ryland P. Byrd, Jr, MD; Thomas M. Roy, MD

Human chorionic gonadotropin (HCG) is typically associated with pregnancy or germ cell tumors.[1] Although it may be detected within the tissue of a variety of malignant tumors by immunohistochemical methods, including primary lung cancers, serum levels are rarely elevated in non-germ cell malignancies.[2,3]

We describe a young lady who presented with chest discomfort and dyspnea. Clinically, she was thought to have deep venous thrombosis. She presumed that she was pregnant since her last mensis was 3 months before admission. She also had breast tenderness similar to that which she had experienced during a previous pregnancy. A serum value for B-HCG suggested that she was 4 to 6 weeks pregnant. Further investigation confirmed that this patient was not pregnant, but had developed a gonadotropin secreting adenocarcinoma of the lung.

Human chorionic gonadotropin is a placental glycoprotein hormone that is normally found in the serum only during pregnancy and immediately postpartum. The first association between B-HCG and tumors was established in 1959.[4] Its secretion by gestational and germ cell tumors is well acknowledged.[5] With continued improvement of histologic tumor markers, the presence of B-HCG has been documented in the tissue of a variety of nontrophoblastic tumors, including breast, ovary, stomach, and liver.[6,7]

A direct link between gonadotropin production and lung cancer has also been established. It is felt that all lung cancers produce detectable tissue levels of B-HCG,[8] but few bronchogenic cancers produce HCG that is detectable in the serum.[9] Symptoms attributable to biologically active B-HCG produced by bronchogenic tumors are rarely documented.[10]

We present a young female patient with elevated serum B-HCG levels that initially were attributed to pregnancy, but were later found to result from the ectopic secretion of this gonadotropin by a primary bronchogenic neoplasm. Measurable serum levels of gonadotropin in this patient broadened the differential diagnosis and affected the direction of the diagnostic work-up.

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Case Report

The patient, a 33-year-old female, was in good health until 3 months prior to admission. At that time, she experienced dyspnea and left chest discomfort. Based on a high probability V/Q lung scan and the presence of a bloody left pleural effusion, pulmonary thromboembolism was suspected. She had clinical evidence of deep vein thrombosis involving the *left* lower extremity. This diagnosis was confirmed by venogram. She was treated with heparin, followed by Coumadin. Reports on the pleural fluid were negative for the presence of microorganisms or malignant cytology.

The current admission occured 3 months after the initial hospitalization and was prompted by complaints of dyspnea on exertion and right calf tenderness. The patient claimed compliance with her Coumadin. Intravenous heparin was started after Doppler ultrasound confirmed the presence of a *right* femoral vein thrombosis.

The patient stated that she was pregnant. She had missed her last 3 menstrual periods. She experienced nausea and breast tenderness similar to that which she had experienced during an earlier pregnancy. A serum B-HCG level was recorded as 2310 mIU/ml, a value consistent with a 4-6 week gestation. This finding generated significant concerns about the potential teratogenic effects of Coumadin on the fetus. The possibility that her deep vein thrombosis was precipitated by pregnancy or possibly a choriocarcinoma was discussed. After explanation of the risks of fetal damage secondary to drug exposure, the patient elected to undergo cervical dilation and curettage. The uterus was devoid of the products of conception or trophoblastic tissue.



Fig 1 — Chest radiograph shows parenchymal consolidation of the upper lobe, diffuse pleural thickening, and pleural effusion in the left lung.

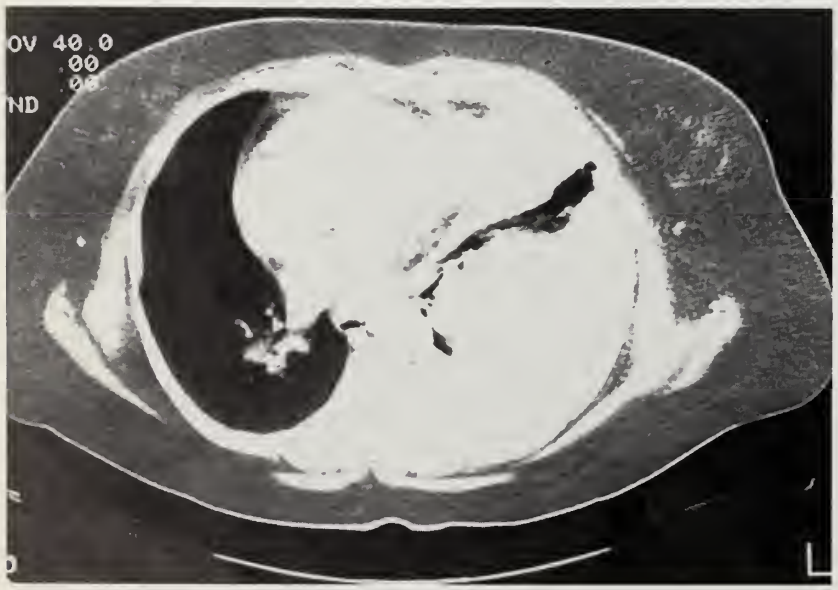


Fig 2 — Computerized tomography of the chest demonstrates almost total obliteration of the left hemothorax.

Assured that the patient was not pregnant, a chest film was performed that demonstrated a left pleural effusion, left pleural thickening, and a suggestion of consolidation of the left upper lung (Fig 1). Computerized tomography of the chest confirmed that the left hemithorax was almost totally obliterated by pleural and parenchymal disease (Fig 2). A bronchoscopy was nondiagnostic. Thoracentesis was attempted, but passage of the needle through the parietal pleura was painful and unsuccessful.

A left thoracotomy was performed through the fifth intercostal space. There was no free pleural space. Tumor was identified all along the markedly thickened parietal pleura. Adhesions prevented optimal examination of the lung parenchyma and mediastinum. A direct pleural biopsy and a wedge resection of the left upper lobe were obtained. The histologic appearance of the tissue suggested mesothelioma or adenocarcinoma. The tumor stained positive for B-HCG (Fig 3). Although electron microscopy supported the diagnosis of mesothelioma, a final diagnosis of adenocarcinoma was assigned because of the tissue's immunoperoxidase activity.

Discussion

Human chorionic gonadotropin is a 40,000 molecular weight glycoprotein composed of two dissimilar noncovalently linked alpha and beta subunits. Although the alpha subunits of human leutenizing hormone and HCG have similar primary structures, the beta subunit has 28 amino acid residues that confer biologic and immunochemical specificity.

The introduction of reliable B-chain radioimmunoassays allows detection of the presence of small amounts of B-HCG in the serum of 4% to 13% of patients with primary bronchogenic carcinoma.[8] The probable mechanism for the appearance of this hormone is derepression of genetic information within malignant cells.[11] As would be expected, the incidence of B-HCG production by lung cancers differs according to the tumor's classification by light microscopy. Small cell carcinoma accounts for the majority of reported cases, followed by large cell carcinoma, squamous cell carcinoma, and finally adenocarcinoma.[8] It is generally felt that the presence of tissue or serum B-HCG is universally absent in patients with malignant mesothelioma.

Interestingly, the presence of detectable B-HCG is usually not associated with symptoms. This observation implies that the hornome may

be biologically inactive. When symptoms do occur, gynecomastia is the most common problem, followed by breast tenderness.[8,9] The ability of circulating B-HCG to stimulate the gonads to produce estrogen may be responsible for amenorrhea in the premenopausal female (our patient).[10] Uterine bleeding in the postmenopausal female is attributed to an estrogen excess that results from transformation of circulating estrogen precursors of adrenal origin.[10]

In most patients with nontrophoblastic neoplasms, the measurable serum level of B-HCG has been modest and without symptoms. Our case is unusual in that an adenocarcinoma produced a level of B-HCG (2200 mIU/ml) that was sufficiently high to suggest the possibility of a pregnancy of 4-6 weeks gestation, or of a trophoblastic tumor.

Although HCG-positive tumors of other organs have been observed to be more aggressive than HCG-negative tumors,[12] it is currently unknown if the presence of serum B-HCG with a bronchogenic carcinoma impacts on prognosis. This area will require further investigation and correlation with the various tumor subtypes.[10] This is now possible by the development of monoclonal immunoradiometric assays and the establishment of a human hepatocellular carcinoma cell line that produces and secretes the beta-subunit of HCG whose physical properties are indistinguishable from the native subunit.[11]

Since HCG is normally present in the serum only during pregnancy, it has been proposed as a compliment to plasma CEA determination in the diagnosis of patients with bronchogenic neoplasms.[14] Although studies of tumor markers continue to suggest that serum B-HCG is of limited use as a diagnostic test, its presence in the serum in any amount in males or postmenopausal females should reinforce the suspicion of a tumor.

In female patients of childbearing age, the presence of this hormonal substance is more problematic. Both pregnancy and choriocarcinoma are more likely in this age group than a nontrophic neoplastic source. Nevertheless, this patient illustrates the need for an expanded differential diagnosis when there are additional pulmonary signs and symptoms. This may become of increasing importance as the incidence of primary lung carcinoma increases in female smokers.

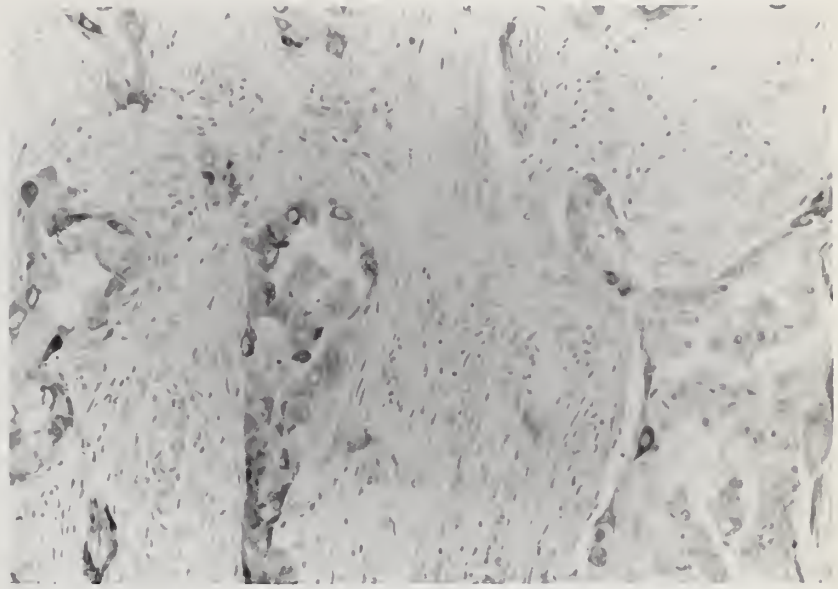


Fig 3 — Tissue from pleural biopsy stained for the presence of B-HCG.

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Correlation Between Clinical, Physical and Laboratory Features in Children With EBV Illness

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The Epstein-Barr virus is one of the most common causes of communicable disease in children. The manifestations of infection may vary with infection, producing mild or inapparent illness or typical features of EBV illness.[1-3] Younger children with primary EBV infection may have a mild self-limited course. Children 3 to 4 years of age may have severe cold symptoms, cough, rhinitis, periorbital swelling, palpable anterior and posterior adenopathy and exudative pharyngitis. Preschool and young school age children may be asymptomatic or have only a mild febrile illness.[2]

Teenagers and young adults with primary EBV infection may develop symptoms of mononucleosis.[1,2] Anorexia, fatigue, abdominal pain, nausea, retroorbital headache, sweats, and chills may last for a few days to several weeks. Then the sore throat worsens and photophobia, puffy face with eyelid edema, petechiae at the junction of the hard and soft palate, exudative pharyngitis, tonsillitis, and adenopathy develop. A maculopapular or petechial rash may occur in 3% to 15% of cases. Severe symptoms may last from 4 days to 3 weeks, then graduatlly resolve. Possible relapses, easy fatigability, and depression may occur during the convalescent phase.[1,2]

This report correlates physical findings and laboratory studies in the diagnosis of EBV infection in children.

Table 1. Age and Gender of Children Suspected of EBV Illness and Month Screened

Patient #	Age (Yrs)	Gender	Month
1	2	F	January
2	3	F	January
3	1½	F	January
4	3*	M	February
5	4	F	December
6	5	F	March
7	2	F	April
8	7	M	April
9	4	M	December
10	6	M	February
11	6	F	December
12	4	M	March
13	19	F	February
14	7*	F	March
15	3	F	March
16	4	F	March
17	1	M	March
18	2	F	March

* Months

Methods

From December 1991 through April 1992, children with a history and physical consistent with EBV illness seen as outpatients in our office were screened with a complete blood count and an EBV profile. The CBC was performed in a hospital clinical lab, and the EBV profile was sent out to a reference lab. The diagnosis of a particular stage for EBV illness was based on the presence of specific profile antibodies, EBV-VCA, IgG, EBV-EA IgG, EBV-NA Ag and EBV-VCA IgM.

Results

Between December and April, 18 children with suspected EBV illness based upon history and physical manifestations were screened with a complete blood count and EBV profile. The age range of this population was between 3 months and 19 years (Table 1). Of the children screened, 12 were female and 6 were male. Twelve of the 18 were 4 years of age and younger. Four of the 6 males and 8 of the 12 females were 4 years of age and younger. Six of the 18 were evaluated in

Table 2. Correlation of Clinical History ond EBV Profile

Patient #	Headache	Sore Throat	Fever	Stomoch Ache	Fatigue/ Feeling Bod	EBV Stage
1	+	+	+	+	+	Acute
2	–	–	+	+	+	Negative
3	–	–	+	–	+	Negative
4	–	–	+	–	+	Convalescent
5	+	+	+	+	+	Acute
6	+	+	+	+	+	Chronic or Relapse
7	–	+	+	–	+	Acute
8	+	+	+	+	+	Acute
9	+	+	+	+	+	Acute
10	+	+	+	+	+	Acute
11	+	+	+	+	+	Acute
12	–	+	+	+	+	Acute
13	+	+	+	–	+	Convolescent
14	–	–	+	–	+	Acute
15	–	+	+	–	+	Acute
16	+	+	+	+	+	Convolescent
17	–	+	+	–	+	Chronic or Relapse
18	–	+	+	–	+	Acute

(+) Positive History
(–) Negotive History

Table 3. Correlotion of Physicol Findings ond EBV Profile

Patient #	Anterior Cervicol Adenopathy	Other Adenopathy	Exudative Pharyngitis/Tonsillitis	EBV Stage
1	+	+	+	Acute
2	+	+	+	Negative
3	–	+	+	Negotive
4	–	+	+	Convolescent
5	+	+	+	Acute
6	+	+	+	Chronic or relapse
7	+	+	+	Acute
8	+	+	+	Acute
9	+	+	+	Acute
10	+	+	+	Acute
11	+	+	+	Acute
12	+	+	+	Acute
13	–	+	+	Convalescent
14	+	+	+	Acute
15	+	+	+	Acute
16	+	+	+	Convolescent
17	+	+	+	Chronic or relapse
18	+	+	+	Acute

(+) Positive Findings
(–) Negotive Findings

the month of March.

A clinical history of headache and stomacheache was difficult to ascertain in younger children, but was a consistent finding in older children with EBV illness (Table 2). All of the children had fever and were noted to either feel bad or have fatigue. Positive profile results were recorded for 10 of the 12 females and all 6 of the males screened.

Children with acute EBV illness consistently have palpable anterior cervical nodes (Table 3). The two children with a negative profile did not have these nodes palpable. Two of the three children with the convalescent stage EBV did not

Table 4. Complicatians and Additianal Symptams in Children with EBV Illness

Patient #	Age (Yr)	Gender	EBV Stage	Other Clinical Manifestatians
1	2	F	Acute	Otitis media, branchialitis
4	3*	M	Convalescent	Branchialitis, atitis media
5	4	F	Acute	URI, vamiting pneumania, sinusitis
6	5	F	Chranic ar relapse	Vasculitis, atitis media
7	2	F	Acute	Sinusitis, strep throat
8	7	M	Acute	None
9	4	M	Acute	Facial edema
10	6	M	Acute	Nane
11	6	F	Acute	Nane
12	4	M	Acute	Facial edema
13	19	F	Convalescent	Vomiting
14	7*	F	Acute	IgG deficiency
15	3	F	Acute	Facial edema, pneumonia with pleural effusion
16	4	F	Canvalescent	Otitis media, vasculitis
17	1	M	Chranic ar relapse	Otitis media, sinusitis Caffey's syndrame
18	2	F	Acute	Sinusitis, vasculitis

* Manths

have palpable anterior cervical adenopathy. Patient #2 did have palpable anterior cervical nodes, but a negative profile.

Three of the children with acute EBV illness had no additional symptoms or complications (Table 4). However, the remaining 13 had a variety including otitis media (5), sinusitis (4), facial edema (3), vasculitis (3), vomiting (2), pneumonia (2), and bronchiolitis (2). One child with pneumonia also had a pleural effusion. The 3 children with vasculitis were also concurrently receiving Ceclor. One child had Caffey's syndrome and another child had underlying IgG deficiency. Most likely both were unrelated to EBV illness.

Most of the children in this study, 11 of the 18 screened and 9 of 16 with positive profiles, had normal white blood cell counts (5,000-10,000) (Table 5). One child with a positive profile had a low white blood cell count, while 6 had an elevated count. Two of the 3 children in the convalescent phase of EBV illness had no atypical lymphocytes. However, the remainder had anywhere from 1% to 13%. Patient #2 was screened 2 weeks into the illness and had a negative profile. However, the other children having the EBV profile became positive as early as 1 week after the family remembered onset of symptoms. For the children with a positive profile, 5 were in home care with exposure to siblings, 5 were at a babysitter's with other children, 3 were in day care, and 3 were in school (Table 6). Eleven of the 16 (nearly 70%) were in a setting where they were exposed to non-sibling children.

Discussion

The diagnosis of Epstein-Barr virus infection is based on clinical manifestations and laboratory studies.[4,5] The peripheral blood smear showing atypical lymphocytes and heterophil tests have been the standard laboratory detection methods. However, the heterophil may be falsely negative in a significant number of younger children and may remain positive in older children for months after infection, producing false positive results.[1,6] More recently, testing of blood for antibody specific for EBV antigen has been developed. This makes it possible to identify the particular stage of EBV illness.

Infections in children with EBV are usually asymptomatic. Children with overt illness may show mild URI or more typical symptoms of infectious mononucleosis. Children may have EBV illness and not infectious mononucleosis. Infectious mononucleosis is a specific clinical condition depending on the age at which primary EBV infection occurs. The presence of palpable anterior cervical nodes was a consistent finding in children with acute EBV illness. It is usually

Table 5. Laboratory Evaluation and Staging of EBV Illness

Patient #	WBC	Atypical Lymphocytes	EBV Stage	Profile Collection (1)
1	8,800	2	Acute	3
2	7,000	3	Negative	2
3	7,100	0	Negative	4
4	8,700	7	Convalescent	6
5	7,300	1	Acute	2
6	6,800	11	Chronic or relapse	12
7	13,500	8	Acute	1
8	12,500	9	Acute	2
9	11,200	1	Acute	3
10	7,800	10	Acute	1
11	10,000	10	Acute	3
12	8,500	13	Acute	1
13	4,300	0	Convalescent	12
14	7,500	8	Acute	3
15	18,200	4	Acute	2
16	6,800	0	Convalescent	8
17	11,200	5	Chronic or relapse	3
18	13,300	8	Acute	2½

1 — Weeks after onset of sympoms

palpable by the seventh day of illness.[6] One child in the study had palpable anterior cervical nodes, but a negative profile. This could be the result of insufficient time for the profile to become positive between onset of the illness and collection of blood. It is possible that another etiology may have been present. Both *Mycoplasma* and CMV could account for the clinical presentation, anterior cervical adenopathy, and negative EBV profile.

Headache, stomachache, fever, sore throat, and fatigue or feeling bad were frequently reported for children in this study with acute EBV illness. Fatigue, lethargy, and headache are early manifestations for EBV illness, and 80% may develop adenopathy, sore throat, and fever.[6] Fever and adenopathy may develop simultaneously. As many as one-third of all individuals with infectious mononucleosis may develop exudative pharyngitis. Supraorbital and upper cheek edema may occur early in one-third of all cases of infectious mononucleosis. It is seen more often in adolescent and older children.

In this study, 75% of the children positive for EBV infection were 4 years of age and younger. This is comparable to other data showing in socially deprived areas about 80% of 5-year-old children and 40% to 50% of children in privileged areas are sero-positive for EBV.[7] Henle and Henle reported that 14% of children 6 months to 5 years of age have had EBV.[8] Most of these infections are inapparent or mild colds. In developing countries, 30% to 70% of childen have acquired EBV by 4 years of age.[9] A predilection for females was noted in the study, but may have been the result of small sample size. Children with a positive profile were more likely to be around unrelated children, either at school, daycare, or at a babysitter.

Table 6. Exposure of Children with EBV Illness to Day Care Setting

Patient #	Age	Gender	Child Care Setting
1	2	F	b
4	3*	M	a
5	4	F	c
6	5	F	a
7	2	F	b
8	7	M	d
9	4	M	a
10	6	M	d
11	6	F	d
12	4	M	c
13	19	F	c
14	7*	F	b
15	3	F	b
16	4	F	b
17	1	M	a
18	2	F	a

* Months
a — Home care, no other childen except siblings
b — Babysitter with other children
c — Day care
d — School

Most of the childen with acute EBV illness had a normal white blood cell count. They were found to have atypical lymphocytes present in the peripheral blood smear. Tamir found that 95% of children with 10% or more atypical lymphocytes had seroconversion for EBV.[10] Children reported here did not routinely have this degree of atypical lymphocytosis, but their presence was a consistent finding in children with acute EBV illness. Atypical lymphocytes are also seen with cytomegalovirus (CMV) and other viral infections, malaria, poisoning, radiation, hepatitis, mycoplasma, malignancies, allergies, and typhoid. Their presence is therefore not specific for EBV infection, but helpful in its presumptive identification.

Children in this study were noted to develop a positive EBV profile within several weeks after onset of symptoms. The antibodies are produced whether a child has symptomatic or asymptomatic EBV infection. It is possible that the children in this report had low grade illness longer than the parents recalled, or they consistently have early production of antibody at detectable levels. Production of EBV specific antibodies may be detected within several weeks after EBV infection.[7]

A variety of complications occurred in children with acute EBV infection. The most frequent complications were otitis media and sinusitis. Young children are more likely to have these occur due to enlargement of the tonsils and adenoids. Three children had a vasculitis and were concomitantly taking Ceclor. Rashes may occur in as many as 5% to 40% of all children with EBV infection.[6] As many as 80% to 100% of children with EBV illness taking Ampicillin may develop a rash. For the three children in the study, the rash may have been a manifestation of the infection, a reaction to Ceclor, or the result of a combination of drug plus viral factors.

One male child concurrently had Caffey's syndrome and a female had IgG deficiency. The child with IgG deficiency did not have a severe course. However, it has been reported for other individuals with immunodeficiencies, especially x-linked immunologic defect, that a fatal course for infectious mononucleosis may occur.[11] Two children had pneumonia and one had a pleural effusion. Other studies have reported up to 5% of children with EBV illness have pneumonia.[6] Unilateral and bilateral effusions may occur.

Results of this study show that with a typical history, presence of palpable anterior cervical nodes, and atypical lymphocytes on the complete blood count, a presumptive diagnosis of EBV illness is possible. The EBV profile is not necessary for initial diagnosis, but may be reserved in diagnosing relapses or infection not showing typical manifestations.

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History Repeats Itself *or* We Have Come Full Circle

"Many outside interests may affect our care of the patient, and this should not occur. I strongly urge everyone to reread the Hippocratic Oath . . ."

These clichés can be applied to many situations. A recent article I read by Nigel Cameron showed an interesting application to medicine. He briefly discussed the origins of the Hippocratic Oath and then showed how we have begun to dismiss these principles.

In ancient Greece, physicians often helped their patients die. If the patient demanded poison from the physician, he complied. Abortion was also liberally practiced. Society not only approved of these practices, but encouraged them.

Hippocrates proposed a clearly different approach. "The oath's ideas of confidentiality, sanctity, philanthropy, and respect for the patient have shaped healthcare for hundreds of years."[1] Margaret Mead stated that "for the first time there was separation of killing and curing."[2]

The practice of medicine based on the Hippocratic Oath has been challenged for many years now, but the opposition seems to be growing. The stand on abortion, beginning with Roe vs Wade, has been in place for many years, and we have seen a violent reaction to this issue. Dr Jack Kevorkian is involved in physician assisted suicides, and two Western States have come close to legalizing euthanasia.

Several ideas present in society are responsible for pushing these topics to the forefront. The first of these is quality of life. A person's value is linked to his productivity.[3] The sanctity of life has been replaced with quality of life. Unfortunately the value of one's life or another's is subject to a variety of judgements. The next is moral relativism. The ethics of a situation are based more on the facts surrounding it than on the act itself.[4] This produces an ethical code that is constantly changing to fit the situation. As a result, most hospitals now have ethics committees to try and resolve these many and varied situations.

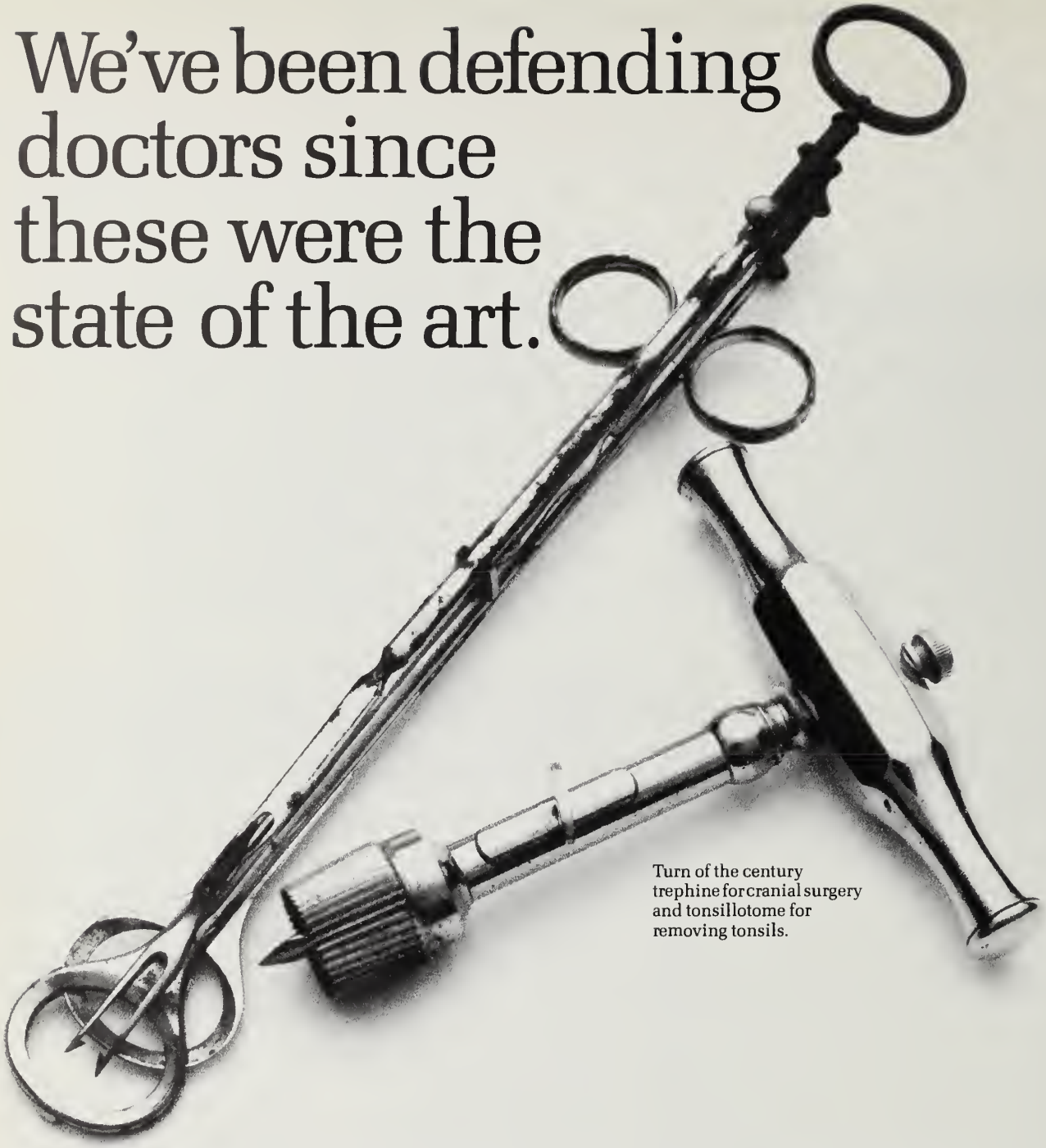
If we allow the above-mentioned ideas to infiltrate our medical system, a slow and steady return to the days before the Hippocratic Oath will occur. We, as doctors, will become contractors to our patients. Many outside interests may affect our care of the patient, and this should not occur. I strongly urge everyone to reread the Hippocratic Oath; let us not come full circle.

William P. Hoagland, MD

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The number of county Presidents-Elect each state is allotted is based on that state's AMA Alliance membership for the previous year. Presidents-Elect attending the October confluence are:

Debbie Davies — McCracken
Ann Robinson — Northern Kentucky
Janice Scherm — Daviess
Ann Wheeler — Fayette
Alice Cowley — Jefferson

Time will be spent updating us on President Clinton's plan for health care reform, as well as what the American Medical Association is doing as the legislation works its way through congress. Speakers for these sessions include Ross Rubin, JD, Vice-President, Legislative Activities AMA, and Kevin Walker, Vice-President, Political Affairs/AMPAC.

The "Health Issues" portion of confluence provides an opportunity to see an innovative program developed by the Fresno-Madera Medical Society Auxiliary of California. The HAP-award winning, live theatre presentation was developed to take to local schools to educate adolescents and teens about AIDS/HIV and other health issues.

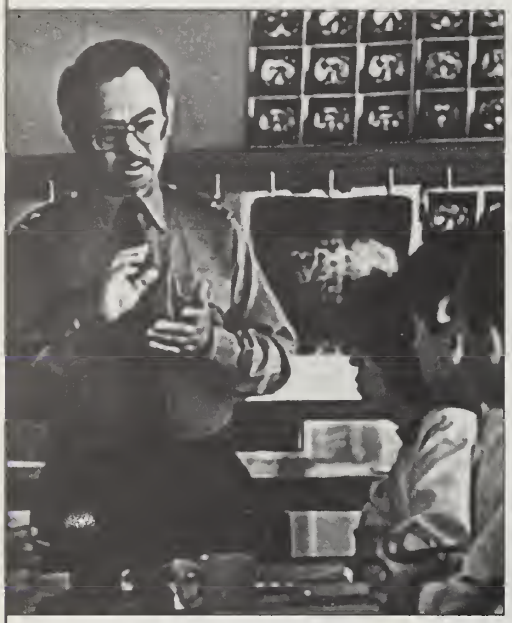
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The Journal

TO THE EDITOR: Next week I will be leaving my profession of the past fifteen years — that of research writer and editor here with Humana and formerly with the University of Kentucky — to take up entirely new opportunities elsewhere, but today I want to tell you how pleased I am with changes you've made in *The Journal* during these years.

The Journal has become a useful publication that reports good science and somehow also manages to represent the crucial interests of the state medical association. Comparing ours to other state journals makes a Kentuckian a bit proud.

My best to you.

Marilyn Wullschleger

Management of Prescribing

TO THE EDITOR: The following article, "Management of Prescribing," was written by Cassius M. C. Ellis, III, MD, Board President of the Minnesota Board of Medical Examiners. The Board has granted permission for publication of this article in the *KMA Journal.*

It's not what you prescribe, but how well you manage the patient's care, and create a record of that care, that's important.

Too many times a physician comes to the Board's attention, and may even be disciplined by the Board, not for using the wrong drug or wrong dosage, but for simply mismanaging the whole prescribing activity.

The prescribing matters that come before the Board are almost always related to the prescription of controlled substances, however, the methodology suggested there applies equally well to prescribing the drug. These suggestions are really the application of common sense to the development of patient care. It may sound like belaboring the obvious, however, I want to assure you that 90% of the physicians who have been disciplined by the Board for prescribing practices could have avoided any problems at all if they had followed the steps that I'm going to outline.

To prevent any misunderstanding, it's necessary to state some things which the Board *does not* have.

It *does not* have a list of "bad" or "disallowed" drugs. All drugs are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

It *does not* have some magic formula for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case, and continued under proper monitoring. What's good for one patient may be insufficient or fatal for another.

What the Board *does* have is the expectation that physicians will create a record that shows:

Proper indication for the use of the drug or, other therapy
Monitoring of the patient
The patient's response to the therapy
All rationale for continuing or modifying the therapy

Step One
First and foremost, before you prescribe *anything*, start with a diagnosis which is supported by a history and physical, and by the results of any appropriate tests. Too many times a doctor is asked why he prescribed a particular drug, and the response is, "Because the patient has arthritis." Then the doctor is asked, "How did you determine that?", and the answer is, "Because that's what the patient complained of." Nothing in the record or in the doctor's recollection supports the diagnosis except the patient's assertion. *Do a workup sufficient to support a diagnosis*, including all necessary tests.

Step Two
Create a treatment plan which includes the use of appropriate nonaddictive modalities, and make referrals to appropriate specialists, such as neurologists, orthopedists, psychiatrists, etc., when appropriate. Include the results of the referral in the patient's chart.

Step Three
Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that *nonaddictive modalities aren't appropriate or that they don't work.* A finding of intolerance or allergy to n-said's is one thing, but the assertion of the patient that "Gosh, Doc, nothing seems to work like that Percodan stuff!" is quite another. Too many of the doctors the Board has seen have started off their treatment program with powerful controlled substances without ever considering other forms of treatment.

Step Four
Make sure you are not dealing with a drug-seeking patient. If you know the patient, review the prescription records in the patient's chart and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum, obtain an oral drug history, and discuss chemical use and family chemical history with the patient.

If you have any doubts, you might consider obtaining a chemical

dependency evaluation prior to prescribing an addictive substance.

Step Five
Obtain the informed consent of the patient before using a drug that has the potential to cause dependency problems. Many drug companies provide patient information brochures for their products which explain the risk benefit considerations in laymen's language. If these brochures are not available, *Professional's Guide to Patient Drug Facts* is available from *Facts and Comparisons.* This publication is a great assistance in counseling patients regarding all medications, not just controlled substances. The AMA also has an excellent series available for distribution to patients. If none of these are available to you, *take the time to explain the relative risks and benefits of the drug based on the materials in the PDR or the AMA's Drug Evaluations.* Also available from most drug companies and medical supply houses are consent forms which provide a format for entering the patient's acknowledgment of the information you have presented and his or her consent to the use of the drug. When embarking on what appears to be a long term use of a potentially addictive substance, it may be wise to hold a family conference and explain the relative risks of dependency or addiction and what that may mean to the patient and to the patient's family.

Refusal of the patient to permit a family conference may be significant information.

Step Six
Maintain regular monitoring of the patient, including regular and frequent physical monitoring. When a patient is on a regimen of controlled drugs, especially if the regimen is a long one, it is very important to monitor the patient for the root condition which necessitates the drug, *AND* for the side effects of the drug itself. This is true, no matter what type of controlled substance is used, or what schedule it belongs to. Also, remember that with certain conditions, drug holidays are appropriate. This allows you to check to see whether the original symptoms reoccur when the drug is not given — indicating a continuing legitimate need for the drug; or whether withdrawal symptoms occur — indicating drug dependence.

Step Seven
Make sure *YOU* are in control of the supply of drug. To do this, at a minimum, you must keep detailed records of the type, dose, and amount of the drug prescribed. You must also monitor, record and control all refills. *One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time.* Records of cumulative dosage and average daily dosage are especially valuable. A thumb nail sketch of three recent cases will illustrate my point here. In the first case, a physician prescribed Tussionex to a patient for approximately 5 years for a cumulative dosage of nineteen and one half GALLONS. In the second case, a physician prescribed Tylenol 3's to a patient for slightly more than a year at the average daily rate of 44 per day! The third case is very similar, except that it was Tylenol 4's at the rate of 30 per day. Some quick observations:

No physician who was aware of that kind of prescribing would have continued with it.

Few, if any, patients could have been consuming that much Tylenol with codeine. In all likelihood, they were reselling it.

Another important part of controlling the supply of a drug is to check on whether the patient is obtaining drugs from other physicians. *Minnesota law allows any current treating physician to have access to a patient's prescription profile.* Checking with pharmacies and pharmacy chains may tell you whether a patient is obtaining extra drugs or doctor shopping.

Step Eight
Maintaining regular contact with the patient's family is a valuable source of information on the patient's response to the therapy regimen, and may be much more accurate and objective than feedback from the patient alone.

You can find out more easily whether the patient actually has improved function, or is just "feeling good" as a result of the drug. A family report of an active and contributing patient is one thing. A family report of a patient spending all his or her waking hours watching soaps is another.

The family is a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is withdrawn. These changes, at either time, may be symptoms of dependency of addiction.

The family is also a good source of information on whether the patient is obtaining drugs from other sources, or is self-medicating, with other drugs or alcohol.

Step Nine
One of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is *inadequate records.* It's entirely possible that the doctor did everything correctly in managing a case, but without records which reflect all the steps that went into the process, the job of demonstrating it to any outside reviewer becomes many times more difficult. Luckily, this is a problem which is solvable. Just as our math teachers always told us — *"Show all your work!"* Make sure the chart reflects each step in the patient workup and treatment program, the patient's response to therapy — in

fact — each of the steps you take in managing the case.

To summarize the points the Board has been presenting over the past several years:

- The necessity to establish an initial diagnosis
- The need for the diagnosis to indicate the use of the particular therapy regimen, no matter what it is
- The need to begin with the least radical therapy and to proceed to the more radical as needed by the individual case
- The need to monitor the patient for both primary symptoms and side effects
- The necessity to make sure that the patient is not a drug seeker
- The need to document all of these steps carefully

The central theme of this article once more is:

What's important is how well you manage a patient's care, and create a record of that care; not what you prescribe.

Melvin Shein, MD
Louisville, KY 40222

Sun Exposure

TO THE EDITOR: Physicians generally advise that sun exposure be avoided, if possible, between 10 AM and 2 PM. It is widely assumed that these are the hours when Ultraviolet B radiation levels are the highest. I have recently begun monitoring Ultraviolet B levels in Cincinnati, Ohio. My early results indicate that we, as physicians, may be giving inaccurate advice.

Ultraviolet B radiation was measured with a Solar light UV-Biometer,[1] at 30 minute intervals from June 18, 1993, to July 18, 1993, on 20 cloudless days. The meter measures the amount of ultraviolet radiation in minimal erythema doses/hour for type 2 (average white) skin. The number of minimal erythemic doses per hour were added for each hour, and averaged for the 30 day period. The results were as follows:

10 AM to 11 AM	— 1.30 MED/HR
11 AM to 12 NOON	— 2.18 MED/HR
12 NOON to 1 PM	— 2.74 MED/HR
1 PM to 2 PM	— 3.26 MED/HR
2 PM to 3 PM	— 3.20 MED/HR
3 PM to 4 PM	— 2.86 MED/HR
4 PM to 5 PM	— 2.01 MED/HR
5 PM to 6 PM	— 1.54 MED/HR

Measurements were consistent day to day, over the 30 day span, and the low readings in the 10 AM to 11 AM interval cannot be blamed, for example, on a series of cloudy mornings. Lower readings in the morning may be due to the use of daylight saving time.

It is apparent from the average readings that we should be advising our patients to avoid the sun much later in the day then we currently do. The amount of UVB from 2 PM to 3 PM in the second highest amount per hour, in the day, and the amount of UVB from 3 PM to 4 PM the third highest. Even the interval from 4 PM to 5 PM will sunburn an untanned patient with average white skin in less than 30 minutes.

Perhaps we should tell patients, and the public, to avoid the sun from 10 AM to 6 PM, or at least continue to use sunscreens and other UVB avoidance measures, until 6 PM.

Brett M. Coldiron, MD, FACP

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Physician Recognition Award Recipients

Listed below are KMA member physicians in Kentucky who have earned the AMA's Physician Recognition Award (PRA) from July 1992 through July 1993.

The Award was established by the AMA House of Delegates of the American Medical Association in 1968 "to encourage physician participation in continuing medical education and to recognize physicians who have voluntarily completed programs of continuing medical education." In December 1992, the AMA House of Delegates revised the requirements for the PRA. Physicians now have two choices for PRA certification — a standard certificate and a new PRA certificate "with Special Commendation for Self-Directed Learning." A minimum of 150 credit hours of CME must be earned over a consecutive 3-year period to qualify for the Standard PRA Certificate. Of these 150 hours, at least 60 must be in AMA/PRA Category 1. Ninety hours of education can be

Agrawal, Mahesh	Louisville
Altman, Harry E.	Pikeville
Arterberry, Joe F.	Louisville
Asher, Christine A.	Trenton
Ball, Christina F.	Louisville
Banerjee, Timir	Louisville
Bark, Joseph P.	Lexington
Barton, Donald C.	Corbin
Barton, Paul B.	Corbin
Bauer, Richard C.	Madisonville
Bautista, Constancio	Mt. Washington
Begley, William G.	Bowling Green
Bhatraju, Rao S.	Pikeville'
Bloom, Steven M.	Louisville
Brashear, Robert M.	Richmond
Briscoe, C. William	Corbin
Bunch, Susan C.	Louisville
Bunge, Robert J.	Lexington
Burkhart, William K.	Lexington
Burress, Susan	Nicholasville
Callen, Jeffrey P.	Louisville
Campbell, Mark R.	Trenton
Cannon, David R.	Louisville
Cash, Ralph L.	Princeton
Chalothorn, Narong	Prestonsburg
Chambers, Henry F.	Campbellsville
Clarke, Jeffrey S.	Paducah
Combs, Kenneth G.	Hopkinsville
Cornelius, Kimberly	Mt. Vernon
Cotthoff, John E.	Hopkinsville
Cummins, Thomas D.	Louisville
Dansby, Karen N.	Ashland
Denison-Humphries, Vinna	Hopkinsville
Edelstein, Stephen G.	Lexington
Eiferman, Richard A.	Louisville
Eisenstein, Warren J.	Glasgow
El Naggar, Amr O.	Somerset
Elbl, Francisco	Louisville
Ellis, Laura T.	Morehead
Emslie, Robert J.	Madisonville
Eubanks, Samuel G.	Louisville
Fitzpatrick, Michael A.	Elizabethtown
Florman, Larry	Louisville
Flowers, Kevin L.	Munfordville
Fox, Martin S.	Louisville
Fraim, Jerry D.	Paintsville
Geren, John W.	Lexington
Giles, Charles S.	Columbia
Goodin, Robert R.	Louisville
Hall, Larry J.	Elizabethtown
Harris, Bill H.	Lexington
Heine, Karl G.	Henderson
Heyburn, Martha K.	Louisville
Hines, John H.	Fairdale
Horner-Taylor, Christine	Edgewood
Howell, Robert S.	Hopkinsville
Hubbuch, Anthony	Louisville
Jackson, Billy G.	Mayfield
Jamison, Jerry L.	Jamestown
Jenkins, Van R.	Lexington
Kerby, Clifford F.	Berea
Kirzinger, Stephen S.	Louisville
Knuckles, Melissa L. F.	Corbin
Kraus, John W.	Paducah
Krumpelman, Jerome L.	Richmond
Leach, Rice C.	Frankfort
Lee, Bothwell G.	Louisville
Leedhanachoke, Oon	Pikeville

in Category 2 which includes CME lectures and seminars not designated Category 1; medical teaching; articles, publications, books, and exhibits; and nonsupervised CME such as self-instruction, consultation, patient care review, and self-assessment. Credit hours are based on hour-for-hour participation in a continuing medical education activity with the number of hours rounded to the nearest whole hour. For the new Special Commendation Certificate, the requirements differ from the Standard Certificate in that applicants cannot include reading of medical literature as qualifying for Category 2 and applicants had to obtain a minimum of 20 credit hours of Category 1 and 20 credit hours of Category 2 annually.

We congratulate these physicians who have distinguished themselves and their profession by their commitment to continuing education.

Lichtenstein, Philip K.	Highland Heights	Smith, Clifton	Lexington
Lichtenstein, Steven J.	Louisville	Smith, Stephen Z.	Louisville
Loeb, Thomas M.	Louisville	Sopko, Robert G.	Ft. Thomas
Longshore, Robert T.	Covington	Sparks, Dennis A.	Louisville
Maguire, Herbert T.	Louisville	Stern, James M.	London
Maldonado, Alberto R.	Louisville	Stigall, Robert W.	Danville
Marshall, Willis H.	Bowling Green	Stulc, Jaroslav P.	Madisonville
Miles, Richard S.	Russell Springs	Suetholz, David W.	Covington
Miller, William L.	Greenville	Swikert, Donald J.	Florence
Mitchell, William H.	Richmond	Tanamachi, Vincent P.	Edgewood
Moberly, Harold S.	Winchester	Tapp, John C.	Bowling Green
Morris, Cathleen M.	Louisville	Tasman, Allan	Louisville
Mortara, Richard H.	Lexington	Tate, Emmett L.	Paris
Nasraty, Soraya P.	Louisville	Taustine, Lloyd R.	Louisville
Nawab, Syed M.	Louisville	Terhune, Jonathan N.	Hopkinsville
Newton, Anne F.	Elizabethtown	Thomas, Robert J.	Ashland
Offutt, William N.	Lexington	Tittel, Paul W.	Goshen
Palmer, Clarkson T.	Frankfort	Tsai, Tsu M.	Louisville
Parker, B. Frank	Louisville	Tucker, Daniel M.	Louisville
Patton, John A. L.	Whitley City	Vaezy-Anzoha, Abdolazim	Corbin
Peck, Charles E.	Russell Springs	Valentini, George R.	Hopkinsville
Peters, Clarence K.	Louisville	Valera, Erlindo G.	Pikeville
Phillips, R. J.	Gilbertsville	Valera, Remedios M.	Pikeville
Plumlee, John E.	Lexington	Waggoner, David C.	Paducah
Quinby, Patricia A.	Louisville	Wells, Raymond D.	Inez
Richard, Henri C.	Radcliff	Wheeler, Max E.	Ashland
Sandler, Nat H.	Lexington	Williams, Wayne E.	Mayfield
Sanfilippo, Joseph S.	Louisville	Wilson, James S. W.	Brownsville
Sarkari, Bahadur	Paducah	Wong, Chris	Florence
Scott, Brian F.	Lebanon	Woodring, Mary A.	Pineville
Seligson, Edwin J.	Ashland	Woolley, Robert B.	Lexington
Sides, Paul J.	Lancaster	Younoszai, Mohammed K.	Louisville
Siegel, Ayn D.	Jackson	Zimmerman, Nathan	Lousiville
Simmons, John W.	Monticello	Zukof, Debra	Lousiville

PEOPLE

James F. Glenn, MD, has been named associate dean for clinical affairs, University of Kentucky College of Medicine (UK), and chief of staff for the University of Kentucky Hospital.

A native of Lexington, Dr Glenn has been a professor of urology in the department of surgery at UK since 1987. He was acting director of UK's Lucille Parker Markey Cancer Center from July 1989 to January 1993.

Dr Glenn received his bachelor's degree from UK in 1946 and graduated with honors from Duke University School of Medicine in 1952.

Chris Pitcock, MD, of the Department of Family and Community Medicine at the University of Louisville has been selected as a winner of a 1993 Mead Johnson Award for Graduate Education for Family Medicine. Over 160 second year family medicine residents nationwide competed for 20 $2000 awards granted by the American Academy of Family Physicians and sponsored by the Bristol-Myers Squibb Company. Dr Pitcock joins an elite group of physicians who represent the most outstanding Family Practice residents in the country, chosen for their achievements and outstanding commitment to family medicine ideals.

John W. Poundstone, MD, Lexington, has been selected as a senior scholar in the Public Health Leadership Institute.

Vipul N. Mankad, MD, is serving as professor and chair of the department of pediatrics at the University of Kentucky College of Medicine. Dr Mankad received his MD from the Medical College of the Maharaja Sayajirao University of Baroda, India.

KMAA Past President **Jo-Ann Daus** was elected President-Elect of the Southern Medical Association Auxiliary in October 1993, at the SMA Auxiliary meeting in New Orleans (meeting in conjunction with the 87th Annual Scientific Assembly of the Southern Medical Association).

KMAA Past President **Esther Jansing** assumed responsibilities as an AMAA Field Director in June 1993.

UPDATES

Lobbying Expenses No Longer Deductible

The Conference Report on the Omnibus Budget Reconciliation Act of 1993 prohibits deductions for expenses relating to lobbying at the federal or state level. Thus, that part of membership dues associated with lobbying expenses which traditionally has been deductible as ordinary and necessary business expenses, will no longer be deductible after January 1, 1994. Therefore, a portion of your 1994 KMA dues may be deductible as professional or business expenses. KMA is tracking these costs and will advise all members at a later date of the percentage of their dues which is not deductible.

Medicare Limiting Charges

Under present Medicare rules, physicians who do not participate must limit charges made to Medicare patients to the "limiting charges."

For services provided in 1991 and 1992, this charge is specific to each physician by profile. For services provided in 1993, nonparticipating physicians may charge no more than 115% of their profile fees. Charges will be reduced to the Medicare allowable payment for all physicians who submit claims for bilateral surgery, multiple dermatological procedures, multiple surgical procedures, and multiple endoscopic procedures.

The Health Care Financing Administration has instituted a Limiting Charge Compliance Program for nonparticipating physicians as an educational effort. Physicians who charge above the limiting charge are being asked to acknowledge errors and make adjustments to their charges based on information developed by the Medicare carrier. These charge adjustments are being requested in lieu of sanctions which may follow.

Some physicians may be exceeding limiting charges because of unfamiliarity with Medicare rules. Specifically, these payment rules relate to bilateral and multiple surgery, dermatological and endoscopic procedures. If anyone is unfamiliar with these charge rules, please consult your provider manual or the Medicare carrier at 606/281-5844.

Breast Cancer Prevention Trial

U of L is participating in a national evaluation of tamoxifen to determine if the drug can prevent breast cancer.

Locally, **John T. Hamm, MD,** associate professor of medical oncology, is principal investigator. The Breast Cancer Prevention Trial is the first large-scale breast cancer prevention trial in the world.

To date 8,000 women, or half the number needed to complete the study, have enrolled. Fifty participants are from Louisville.

Research has shown that taking tamoxifen pills after surgery for breast cancer prevents recurrence of the disease and increases survival rates.

Women aged 35 and older who are at increased risk for developing breast cancer are eligible to participate in the double-blind study. This risk level is based on the formula

that includes family history and other established factors.

Divided into groups randomly, half of the women in the trial take tamoxifen and half take a placebo every day for at least 5 years.

The study is primarily funded by the National Cancer Institute and endorsed by the American Cancer Society and numerous breast cancer patient advocacy groups.

"We are very pleased with the women who have entered. They are very dedicated," Dr Hamm said. For the 8,000 women enrolled, researchers note that the drug has been well tolerated.

Dr Hamm also said that women enrolled thus far have a predicted risk of developing breast cancer that is, on the average, almost five times greater than women with no risk factors.

As researchers expected, trial participants taking tamoxifen have experienced few toxicities or serious drug reactions though some participants have experienced symptoms such as hot flashes.

Women participating in the study report that they appreciate the careful follow-up and testing that is required, including the monitoring of their quality of life.

In addition to its focus on breast cancer, the study addresses whether tamoxifen reduces deaths due to heart attacks and reduces bone fractures in women.

In women taking the drug for breast cancer, some studies have shown their total cholesterol was significantly reduced. This may result in a reduction of heart attacks and strokes, researchers surmise.

NEW MEMBERS

Members of the Kentucky Medical Association and their respective county medical societies join in welcoming the following new members to these organizations.

Boyd

William J. Short, MD — FP
2703 Irish Oaks Dr, Ashland 41102
1990, U of Kentucky

Bourbon

Carl H. Rosen, MD — U
6 Linville Dr, Paris 40361
1972, U of Texas, Dallas

Fayette

Carleton T. Anderson, MD — PTH
PO Box 680, Lexington 40586
1968, U del Litorall, Argentina

Kimberly A. Dixon, MD — FP
1221 S Broadway, Lexington 40504
1990, U of Kentucky

Charles A. Kennedy, MD — IM
1221 S Broadway, Lexington 40504
1985, U of S California

Alberto N. Laureano, MD — OTO
1221 S Broadway, Lexington 40504
1987, U of Pennsylvania

Suzanna I. Park, MD — IM
1221 S Broadway, Lexington 40504
1985, U of Kentucky

Scott T. Pierce, MD — IM
3275 Waterford Pk, Lexington 40517
1988, U of Illinois

David B. Richards, MD — ORS
1221 S Broadway, Lexington 40504
1987, U of Texas, San Antonio

Christopher R. Swayze, MD — AN
1800 Nicholasville Rd, Lexington 40503
1988, LSU, Shreveport

Hong I. Tjoa, MD — C
1221 S Broadway, Lexington 40504
1985, Rutgers

Hopkins

Michael L. Lewis, MD — OBG
Trover Clinic, Madisonville 42431
1982, U of S Florida

Jessamine

Cynthia D. Croy, MD — FP
201 S Lexington Ave, Wilmore 40390
1990, U of Missouri

Lawrence

Michael J. Pravetz, MD — P
PO Box 366, Louisa 41230
1982, King Edward Med School, Pakistan

Northern Kentucky

Patrick T. Birrer, MD — EM
7370 Turfway Rd, Florence 41042
1988, NY Medical College

Christopher F. Bolling, MD — PD
2865 Chancellor #225, Crestview Hills 41017
1987, U of Cincinnati

Olivia Y. Wallace, MD — PD
20 Medical Village Dr, Edgewood 41017
1987, U of Kentucky

Pulaski

Abdel-Malec Mokraoui, MD — C
349 Bogle St, Somerset 42501
1976, Karolinska Institute, Sweden

Scott

Frank L. Denoff, MD — ORS
1140 Lexington Rd #102, Georgetown 40324
1983, U of Miami

Warren

James R. Hansbrough, MD — PUD
201 Park St, Bowling Green 42102
1983, Washington U, Saint Louis

Whitley

Vickie C. Whobrey, MD — PMR
1931 Mallard Dr, London 40741
1989, U of Kentucky

In-Training

Victor M. Montes-Jordan, MD — HEM

DEATHS

Robert J. Hoffmann, MD
Covington
1918-1993

Robert J. Hoffmann, MD, a retired family practitioner, died July 16, 1993. Dr Hoffmann graduated from the University of Cincinnati College of Medicine in 1942 and was a life member of KMA.

Frank M. Reinecke, Jr, MD
Louisville
1934-1993

Frank M. Reinecke, Jr, MD, an anesthesiologist, died September 6, 1993. A 1963 graduate of the University of Louisville School of Medicine, Dr Reinecke was an active member of KMA.

John R. Gott, Jr, MD
Louisville
1906-1993

John R. Gott, Jr, MD, a retired internist, died September 19, 1993. Dr Gott graduated from the University of Louisville School of Medicine in 1929. He was instrumental in organizing the Louisville Society of Internists and served as its first president in 1950. Doctor Gott was also listed in "Who's Who in the South and Southwest." He was a life member of KMA.

Arthur T. Hurst, MD
Louisville
1901-1993

Arthur T. Hurst, MD, a retired internist, died September 22, 1993. He graduated from the University of Louisville School of Medicine in 1925. Dr Hurst was a past president of the Jefferson County Medical Society and a life member of KMA.

James G. Boggs, MD
Russell
1913-1993

James G. Boggs, MD, a retired family practitioner, died October 4, 1993. Dr Boggs graduated from Middlesex University School of Medicine in 1942 and was a life member of KMA.

Arthur R. Kasey, MD
Louisville
1909-1993

Arthur R. Kasey, MD, a retired psychiatrist, died October 5, 1993. Dr Kasey was a 1935 graduate of the University of Louisville School of Medicine. He was the first director of the state Health Department's Mental Hygiene Division, and was a former chairman of the state Advisory Council on Mental Health, on which he served several terms. Dr Kasey was a life member of KMA.

PHARMACEUTICALS AVAILABLE TO KENTUCKY PHYSICIANS CARE

These Pfizer/Roerig/Pratt & Searle pharmaceuticals may be prescribed and dispensed under the program:

Pfizer Labs

Antiminth® (Pyrantel pamaate) OTC
Cartril® Tapical Ointment 1% (Hydracartisane) Rx
Diabinese® Tablets (Chlarprapamide) Rx
Diabinese® Tablets Unit-Dase Pak (Chlarprapamide) Rx
Feldene® Capsules (Piraxicam) Rx
Feldene® Capsules Unit-Dase Pak (Piraxicam) Rx
Minipress® Capsules (Prazasin HCl) Rx
Minipress® Capsules Unit-Dase Pak (Prazasin) Rx
Minizide® 1 Capsules (1 mg. Prazasin and 0.5 mg. Palythiazide) Rx
Minizide® 2 Capsules (2 mg. Prazasin and 0.5 mg. Palythiazide) Rx
Minizide® 5 Capsules (5 mg. Prazasin and 0.5 mg. Palythiazide) Rx
Maderil® Tablets (Rescinnamine) Rx
Narvasc® (2.5, 5 and 10 mg.) Rx
Renese® Tablets (Palythiazide) Rx
Renese®-R Tablets (2 mg. Palythiazide and 0.25 mg. Reserpine) Rx
Sustaire® (Theaphylline anhydraus) Rx
Terramycin® Capsules (Oxytetracycline HCl) Rx
Vansil™ Capsules (Oxamniquine) Rx
Vibra-Tabs® (Daxycycline hyclate) Rx
Vibra-Tabs® Unit-Dase Pak (Daxycycline hyclate) Rx
Vibramycin® Calcium Syrup (Daxycycline calcium aral suspensian) Rx
Vibramycin® Hyclate Capsules (Daxycycline hyclate) Rx
Vibramycin® Hyclate Capsules Unit-Dase Pak (Daxycycline hyclate) Rx
Vibramycin® Manahydrate far Oral Suspensian (Daxycycline manahydrate) Rx
Vistaril® Capsules (Hydraxyzine pamaate) Rx
Vistaril® Capsules Unit-Dase Pak (Hydraxyzine pamaate) Rx
Vistaril® Oral Suspensian (Hydraxyzine pamaate) Rx
Zithramax® Capsules (Azithramycin)

Roerig

Antivert® (Meclizine HCl) Rx
Antivert® Tablets Unit-Dase Pak (Meclizine HCl) Rx
Atarax® (Hydraxyzine HCl) Rx
Atarax® Tablets Unit-Dase Pak (Hydraxyzine HCl) Rx
Banine® Chewable Tablets (Meclizine HCl) OTC
Cardura® Tablets (Daxazasin Mesylate) Rx
Cefabid® (Cefaperazane sodium) Rx
Diflucan® (Flucanazane) Oral and Parenteral Antifungal Rx
Diflucan® (Flucanazane) Unit-Dase Pak Oral and Parenteral Antifungal Rx
Emete-can® IM/IV (Benzquinamide HCl) Rx
Geacillin® (Carbenicillin indanyl sodium) equivalent ta 382 mg. carbenicillin Rx
Geapen IM/IV (Carbenicillin disadium) Rx
Heptuna® Plus Capsules (Iran plus vitamins and minerals) Rx
Hydracartisane Pawder (Hydracartisane USP micranized) Rx
Isaject® Permapen® (Penicillin G benzathine) Aqueaus Suspensian Rx
Marax® (Hydraxyzine HCl [ATARAX®]-Theophylline-ephedrine suffate) Rx
Navane® Capsules (Thiathixene) Rx
Navane® Capsules Unit-Dase Pak (Thiathixene) Rx
Navane® Cancentrate (Thiathixene HCl) Rx
Navane® Intramuscular (Thiathixene HCl) Rx
Pfizerpen® far Injectian (Penicillin G patassium) Buffered Rx
Pfizerpen®-AS (Penicillin G procaine) Aqueaus Suspensian Rx
Palymyxin B Sulfate Sterile Rx
Sinequan® Capsules (Daxepin HCl) Rx
Sinequan® Capsules Unit-Dase Pak (Daxepin HCl) Rx
Sinequan® Capsules Unit af Use Pak (Daxepin HCl) Rx
Sinequan® Oral Cancentrate (Daxepin HCl) Rx
Spectrabid® Oral Suspensian (Bacampicillin HCl) Rx
Spectrabid® Tablets (Bacampicillin HCl) Rx
Streptamycin Sulfate Rx
Taa® Capsules (Traleandamycin) Rx
Terra-Cartril® Ophthalmic Suspensian (Oxytetracycline HCl and hydracartisane acetate) Rx
Terramycin® Intramuscular Salutian (Oxytetracycline) Rx
Terramycin® Ophthalmic Ointment with Palymyxin B Sulfate (Oxytetracycline HCl with palymyxin B sulfate) Rx
Terramycin® Vaginal Tablets with Palymyxin B Sulfate (Oxytetracycline HCl with palymyxin B sulfate) Rx
Unasyn® (Ampicillin sadium/sulbactam sadium) Rx
Urabiatic® 250 (250 mg. Oxytetracycline HCl 250 mg. sulfamethizale 50 mg. phenazapyridine HCl) Rx
Vibramycin® Intravenaus (Daxycycline hyclate far injectian) Rx
Vistaril® Intramuscular Salutian (Hydraxyzine HCl) Rx
Vistaril® Intramuscular Salutian Unit-Dase Vials (Hydraxyzine HCl) Rx
Zalaft® Tablets (Sertraline) Rx

Pratt Division

Glucatral® Tablets (Glipizide) Rx
Glucatral® Tablets Unit-Dose Pak (Glipizide) Rx
Feldene® Capsules (Piraxicam) Rx
Feldene® Capsules Unit-Dase Pak (Piraxicam) Rx
Pracardia® Capsules (Nifedipine) Rx
Pracardia® Capsules Unit Dase Pak (Nifedipine) Rx
Pracardia XL® (Nifedipine) Extended Release Tablets Rx
Pracardia XL® (Nifedipine) Extended Release Tablets Unit-Dase Pak Rx
Zalaft® Tablets (Sertraline) Rx

Searle

Aldactazide® tablets (spiranalactane with hydrachlarathiazide)
Aldactane® tablets (spiranalactane)
Calan® SR caplets (verapamil HCl)
Calan® caplets (verapamil HCl)
Cytatec® tablets (misaprastal)
Kerlane® tablets (betaxalal HCl)
Nitradisc® discs (nitraglycerin)
Narpace® capsules (disapyramide phasphate)
Narpace® CR capsules (disapyramide phasphate)

PHARMACEUTICALS AVAILABLE TO KENTUCKY PHYSICIANS CARE

These Johnson & Johnson pharmaceuticals may be prescribed and dispensed under the program:

Iolab Corporation

Argyrol® S.S. (mild silver protein)
Atropisol®Ophtholmic Solution (otrapine sulfote)
Cotorose® (chymotrypsin)
Dexocidin® Ophtholmic Suspensian ond Ointment (dexomethosone, neamycin ond polymyxin B. sulfotes)
Dexomethosone Sadium Phasphote Ophtholmic Solution 0.1%
Dexomethosane Sadium Phosphote 4 mg/ml (for injection)
Epinephrine
E-PILO® Ophtholmic Solution (epinephrine bitortrote-pilacarpine HCl)
Eserine Sulfote Sterile Ophtholmic Solutian
Fluorescein Sodium
Fluor-Op® Ophtholmic Suspension (fluarometholone .1%)
Funduscein® -10, -25 Injection (fluorescein sodium)
Gentacidin® Solution ond Ointment (gentomicin sulfote)
Gentomicin 40 mg/ml, 80 mg/2 ml (for injection)
Glucose-40 Sterile Ophtholmic Ointment
Homotropine Hydrobromide
Inflomose® Forte Ophtholmic Solution (prednisolone sodium phosphote)
Inflamose® Mild Ophtholmic Solution (prednisolane sodium phasphote)
Iacare® Balonced Solt Solution
Miochol® Intraacular & System Pok (acetylchaline chloride)
Neamycin, Polymyxin B sulfotes, ond Hydracortisone Ophthalmic Suspensian
Neomycin, Polymyxin B sulfates, ond Gromidicin Ophthalmic Solution
Neomycin Sulfote/Dexomethosone Sodium Phosphote Ophthalmic Salution
Phenylephrine HCl 10%/2.5%
Pilocor® Ophtholmic Solution (pilocorpine HCl)
Sulf-10® Ophtholmic Salution (sodium sulfocetomide)
Tetrocoine HCl
Vosocidin® Ophtholmic Solution (sulfocetomide sodium-prednisolone sodium phasphote) & Ointment (sulfocetomide sodium-prednisolone acetote)
Vosocon-A Ophtholmic Solution (nophozoline HCl-antozoline phosphote)
Vosacon Regulor Ophtholmic Solution (nophozoline HCl 0.1%)
Vososulf® Ophtholmic Solution (sulfocetomide sodium-phenylephrine HCl)

Janssen Pharmaceutica, Inc.

*Durogesic® Tronsdermal system (fentanyl)
Ergomisal® Toblets (levomisole HCl)
Hismonol® Toblets (ostemizole)
Imodium® Copsules (loperomide HCl)
Nizorol® Cream (ketoconozole)
Nizorol® Shompoo (ketoconozole)
Nizorol® Toblets (ketoconozole)
Vermox® Toblets (mebendozole)

McNeil Consumer Products Company

Chemet® Copsules (succimer)
Pedioprofen™ Suspension (ibuprofen)

McNeil Pharmaceutical

Floxin® Toblets (ofloxocin)
Holdol® Toblets ond Concentrote (holoperidol)
Holdol® Deconoote Injection (holoperidol)
Poncrease® Copsules (poncrelipose)
Poncrease® MT Copsules (poncrelipose)
Poraflex® Coplets (chlorzoxozone)
Porofon Forte® DSC Coplets (chlorzoxozone)
Tolectin® Copsules ond Toblets (tolmetin sodium)
Tylenol® with Codeine Toblets and Elixir (ocetaminaphen ond codeine phosphote)
*Tylox® Copsules (oxycodone hydrochlaride and acetominophen copsules USP)
Vascar® Tablets (bepridil HCl)

Ortho Biotech

Procrit® Injection (epoetin Alfo)

Ortho Pharmaceutical Corporation

Aci-Jel® Therapeutic Voginol Jelly
Flaxin® Toblets (ofloxocin)
Micronor® Toblets (norethindrone)
Modicon® Toblets (norethindrone/ethinyl estrodiol)
Ortho® Dienestrol cream (dienestral)
Ortha-Novum® Toblets (norethindrone/mestronol) or (norethindrone/ethinyl estrodiol)
Pratostat® Tablets (metronidozole)
Sultrin® Triple Sulfo Creom ond Voginal Toblets (sulfothiozole/sulfocetomide/sulfobenzomide)
Terozol® Creom ond Voginol Suppasitaries (terconozole)
Erycette®Topicol Solution (erythromycin)
Grifulvin V® Tablets/suspensian (griseofulvin microsize)
Meclan® Cream (meclacycline sulfosolicylote)
Monistat Derm® Creom (miconozole nitrate)
Perso-Gel® & Perso-Gel®W (benzayl peroxide)
Retin-A® Cream/Gel/Liquid (tretinoin)
Spectazale® Creom (econozole nitrate)

*Duragesic® ond Tylax® (CII contralled substances) will be replaced with other products.

PHARMACEUTICALS AVAILABLE TO KENTUCKY PHYSICIANS CARE

These Abbott Laboratories and Novo Nordisk pharmaceuticals may be prescribed and dispensed under the program:

Abbott Laboratories

Biaxin™ Toblets (clorithromycin)
Cartral® Filmtob® Toblets (corteolol HCl)
Cylert® Toblets C^{IV} (pemoline)
Depokote® Sprinkle Copsules (divalpraex sadium)
Depokate® Toblets (divalproex sodium delayed-releose toblets)
Enduran® Toblets (methyclathiazide toblets, USP)
Enduronyl® Toblets (methyclothiozide ond deserpidine)
E.E.S. 400® Filmtob® (erythramycin ethylsuccinate tablets, USP)
E.E.S.® Granules (erythromycin ethylsuccinate far orol suspension, USP)
E.E.S.® 200 Liquid (erythromycin ethylsuccinote orol suspension, USP)
E.E.S.® 400 Liquid (erythramycin ethylsuccinate oral suspension, USP)
Eryderm® (erythromycin tapicol solution, USP 2%)
Eryped® Chewoble Toblets (erythromycin ethylsuccinote toblets, USP)
Eryped® Drops (erythromycin ethylsuccinote for orol suspension, USP)
Eryped® 200 (erythromycin ethylsuccinote for orol suspension, USP)
Eryped® 400 (erythromycin ethylsuccinote for orol suspension, USP)
Ery-Tob (erythromycin deloyed-releose toblets, USP, enteric-cooted)
Erythrocin® Steorote Filmtob® (erythromycin steorote toblets, USP)
Erythromycin Bose Filmtob® (erythromycin toblets, USP)
Fero-Folic-500® Filmtob (controlled-releose iron with vitomin C ond folic ocid)
Fera-Gradumet® Filmtob (controlled-releose dose of iron)
Hytrin® Tablets (terozasin hydrochlaride tablets)
Iberet® Filmtob® (cantrolled-releose iran, vitamin C and B-complex vitomins)
Iberet®-500 Filmtob® (controlled-releose iran with vitomin B-complex ond vitomin C)
Iberet-Falic-500® Filmtob® (controlled-release iron with vitomin C ond B-complex vitomins including folic ocid)
Iberet®-Liquid Orol Suspensian (iran, B-camplex vitamins and vitomin C)
Iberet®-500 Liquid Orol Salutian (iran, B-complex vitomins ond vitomin C)
K-Lor™ 20 mEq. Powder Pockets (potossium chloride for orol suspensian, USP)
K-Lor™ 15 mEq. Powder Packets (patossium chloride for orol suspensian, USP)
K-Tob® 10 mEq. (750 mg.) (potossium chloride extended-releose toblets, USP)
Ogen® Vaginal Cream (estrapipate voginol cream, USP)
Ogen® .625 Tablets (estrapipote toblets, USP)
Ogen® 1.25 Toblets (estropipote toblets, USP)
Ogen® 2.5 Toblets (estropipote toblets, USP)
PCE® 333 mg. Toblets (erythromycin particles in toblets)
PCE® 500 mg. Tablets (erythramycin particles in toblets)
Prosom™ Toblets C^{IV} (estozolom toblets)
Surbex® Filmtob® (vitomin B-camplex)
Surbex® with C Filmtob® (vitomin B-complex with vitamin C)
Surbex-T® Filmtob® (high-potency vitomin B-complex with vitamin C)
Surbex® 750 with Iron Filmtob® (high-potency B-complex with iran, vitomin E ond 750 mg. of vitomin C)
Surbex® 750 with Zinc Filmtob® (zinc, vitomin B-complex ond vitomins C ond E)
VI-Doylin®/F Multivitomin Chewoble Toblets
VI-Doylin®/F Multivitamin + Iron Chewoble Toblets
VI-Doylin® Multivitomin Chewoble Toblets
VI-Daylin® Multivitamin + Iran Chewable Toblets
VI-Daylin® Multivitamin Draps
VI-Doylin® ADC Vitomins Drops
VI-Doylin®/F Multivitomin Drops
VI-Doylin®/F ADC Vitomins Drops
VI-Doylin® Multivitomin plus Iron Drops
VI-Doylin® ADC Vitomins plus Iron Drops
VI-Doylin®/F Multivitomin plus Iron Drops
VI-Daylin®/F ADC Vitomins plus Iron Draps
VI-Daylin® Multivitamin Liquid
VI-Daylin® Multivitamin plus Iran Liquid

Novo Nordisk

HUMAN INSULIN (recombinont DNA origin)

Novolin® R
Novolin® L
Navalin® N
Novolin® 70/30
Novolin® R PenFill®
Novolin® N PenFill®
Novolin® 70/30 PenFill®

HUMAN INSULIN (semi-synthetic)

Velosulin® Human
Insulatord® Human
Mixtord® Humon 70/30

PURIFIED INSULIN

Regular-R
Lente® L
NPH-N
Velasulin® R
Insulatard® N
Mixtard® 70/30

STANDARD INSULIN

Regular-R
Lente® L
NPH-N
Semilente® S
Ultralente® U

PARTICIPATING PHARMACIES
KPC PHARMACY PROVIDER PROGRAM

Adair
DBA Columbia Pharmacy
Madisan Square Drugs & Chymist

Allen
Carpenter Dent Drugs
Stovall Prescriptian Shop
Williams Pharmacy

Andersan
The Medicine Shappe
Reliable Drugs

Ballard
Wickliffe Pharmacy, Inc

Barren
Ely Drugs, Inc
Glasgaw Prescriptian Center
K-Mart Pharmacy
Tawne & Cauntry Drugs

Bell
City & Caunty Drug
Farris Drugs
Jeff's Pharmacy
K-Mart Pharmacy
Krager Campany
Pineville Has. Out-Pt Pharmacy
Rxca Friendly Pharmacy
SuperX Drugs
Tatal Ɍ Care Pharmacy

Boone
Boone Caunty Drugs
Burlingtan Pharmacy
K-Mart Pharmacy
SuperX Drugs
Turfway Pharmacy

Baurbon
Glen's Drugs
Harne's Ardrey Drug
The Medicine Shappe

Bayd
K-Mart Pharmacy
Laynes Pharmacy
McMeans Pharmacy
Reliable Drugs
SuperX Drugs

Bayle
Grider Pharmacy
K-Mart Pharmacy
Leake Pharmacy
SuperX Drugs
Taylar Drug

Bracken
Dean's Pharmacy

Breathitt
Jacksan Prescriptian Ctr
Reliable Drugs

Breckinridge
Save-Rite Drugs
Tawne & Cauntry Pharmacy

Bullitt
Taylar Drugs

Caldwell
Payless Discaunt Pharmacy
The Pharmacy Carner Enterprise

Callaway
Clinic Pharmacy
Halland Drugs
Reliable Drugs
Safe-T Discaunt Pharmacy
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PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administerad to woman of childbaaring age only when such patients are highly unlikaly to conceiva and have bean informed of tha potantial hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Livar Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with ranal dysfunction secondary to myoglobinuria has been raported with pravastatin and othar drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin tharapy should be discontinuad if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin tharapy should also ba temporarily withhald in any patiant axperiancing an acuta or sarious condition predisposing to the davalopmant of ranal failura secondary to rhabdomyolysis, e.g., sepsis; hypotansion; major surgary; trauma; severe matabolic, endocrine, or electrolyta disorders; or uncontrollad epilapsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alona may occasionally be associated with myopathy. The combined usa of pravastatin and fibrates should ganerally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual vanability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover tnal involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with aspirin, antacids [1 hour pnor to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid, or probucol*, no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropnately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallenan-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenasis, Mutaganasis, Impairmant of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed in *vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothars: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **Ganaral**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse expenences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Advarse Clinical Evants: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Tast Abnormalitias: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

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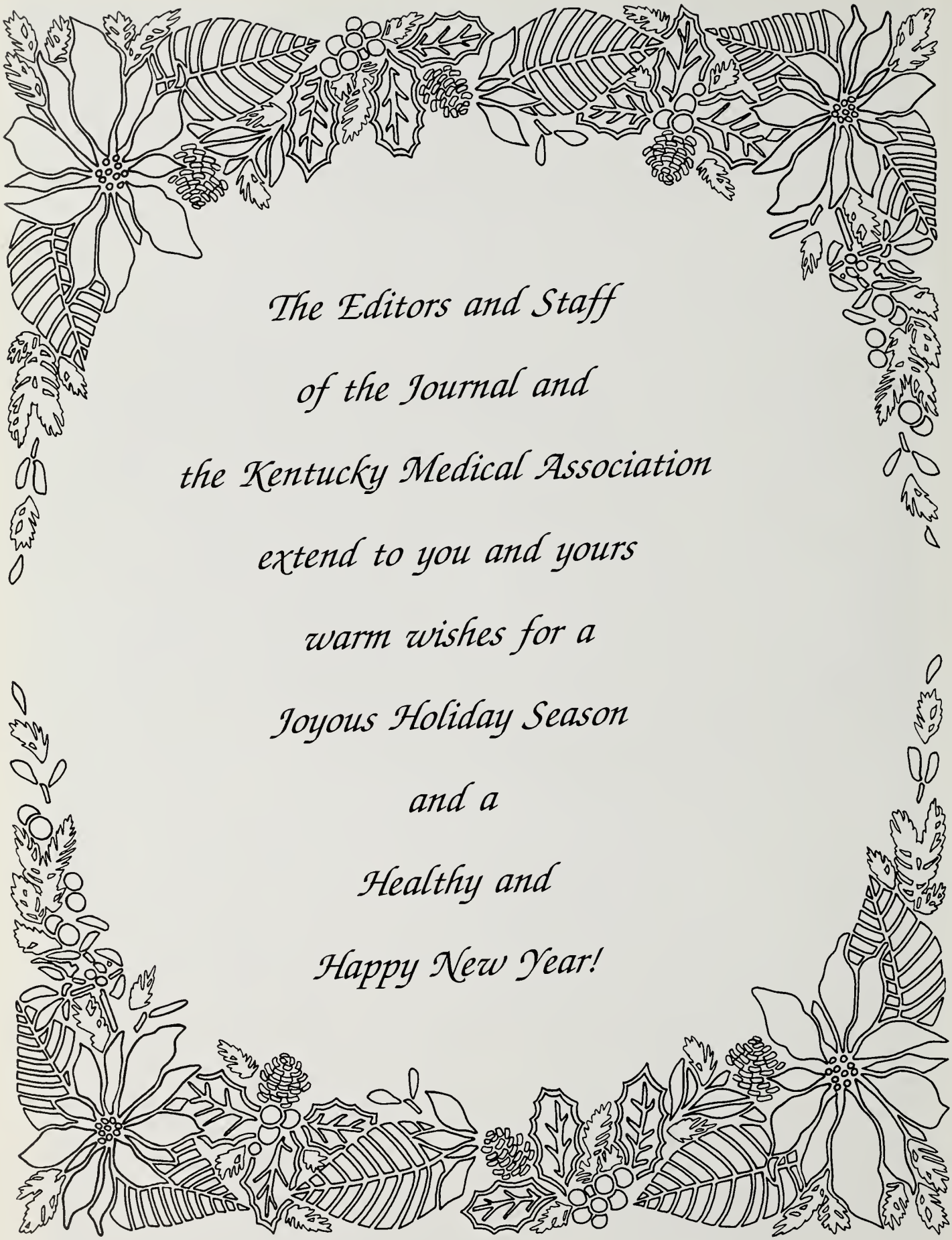
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VOLUME 91, NUMBER 12 DECEMBER 1993

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COVER: This issue of the Journal provides extensive coveroge of the 1993 KMA Annual Meeting, which wos held in Louisville on September 26-30. An overview begins on page 548, with House of Delegotes coveroge beginning on page 565. Cover ort by Lee Wode of Louisville.

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Public Education Committee

"This program should involve all KMA members and requires the support of each of us if it is to be successful."

At the Kentucky Medical Association Annual Meeting in September, a very important and timely issue was addressed by the House of Delegates. Recognizing that the physician and the profession of medicine have perhaps lost some credibility in the community at large, and recognizing that the role of physician care giver in this era of health systems reform has the potential for significant modification, the delegates voted to develop a Public Education Committee which is to be organized on a permanent basis until the House of Delegates believes its activities are no longer necessary.

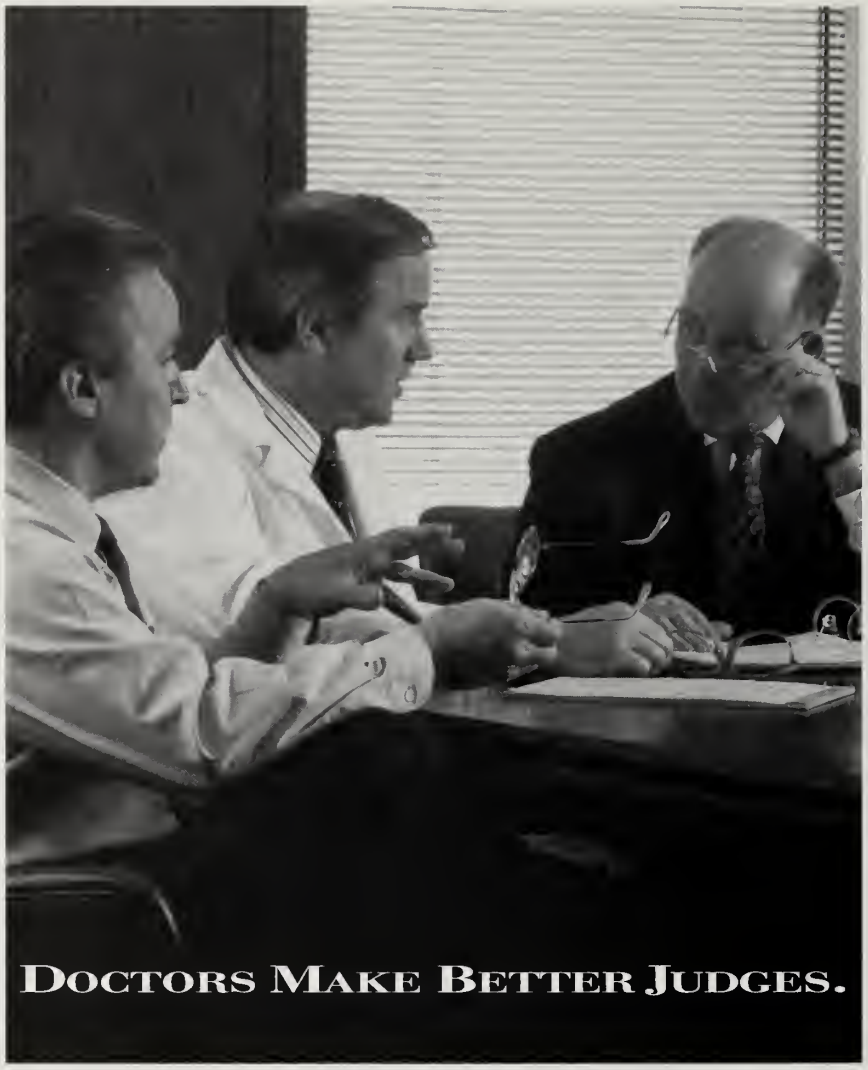
This initiative brought to the floor of the House by the membership is to be funded by a $30 dues increase which will be specifically dedicated to this project. To facilitate this effort, a special committee has been formed and charged with proceeding in a timely fashion with the development of a public education program which will not only inform the citizens of the Commonwealth of the true role and commitment of physicians and the profession of medicine, but also educate them as to what health systems reform really means and how their health care in the future might be affected by the legislative efforts at the state and national level. One of the imperatives of this special group will be to bring the information and programs home to the local community level in a true "grass roots" effort.

This activity will, however, not be limited to the Committee or one or two leaders in the medical community of a given area. This program should involve all KMA members and requires the support of each of us if it is to be successful. The term public relations is a meaningful one. However, I would suggest that the "P.R." stand for personal responsibility in this effort.

A part of that personal responsibility is a commitment to maintaining growth in the membership of the Kentucky Medical Association. Our membership numbers increase and we are encouraged by the response. Now, more than ever, is the time appropriate for committed contribution and active participation — not only at the state level, but in the county medical societies. I commend the membership for its enthusiasm and dedication to the efforts being initiated.

I wish for all of you, your families, and loved ones a very special and happy holiday season. May the new year bring us closer to achieving our dreams and goals for the health of our patients and our profession.

Seasons Greetings!
Ardis D. Hoven, MD



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To laugh often and much; to win the respect of intelligent people and the affection of children; to earn the appreciation of honest critics and endure the betrayal of false friends; to appreciate beauty; to find the best in others; to leave the world a bit better, whether by a healthy child, a garden patch, or a redeemed social condition; to know one life has breathed easier because you lived; this is to have succeeded.

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List of deceased physicians available to the *Journal* as of August 1, 1993.

Primary Spontaneous Pneumothorax
Therapeutic Considerations

Ryland P. Byrd, Jr, MD; Mary Nicole Risner, MD; Harvy L. Snider, MD; Thomas M. Roy, MD

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Primary pneumothorax represents the single most frequent cause of admission of young adults to a hospital's thoracic service.[1] However, the best management of these patients with rupture of subpleural blebs in the apical region remains controversial.

In a retrospective analysis of 108 consecutive patients with spontaneous primary pneumothorax treated at a university hospital over a 5-year period, we were able to examine the risks and benefits of various treatment approaches. Interestingly, although male patients outnumbered female patients approximately 2:1, female patients were statistically more likely to undergo operative intervention.

Idiopathic spontaneous pneumothorax typically results from the rupture of an air-circulating bleb that lies immediately below the visceral pleura and is unrelated to trauma, malignancy, or infection. It is generally a problem of young adults, especially cigarette smokers, and occurs with an incidence of approximately 5 cases per 10,000 patient admissions.[2]

Although the etiology of spontaneous primary pneumothorax has been well established, there is less agreement about the best mode of therapy to accomplish adhesion between the visceral and parietal pleura that will maintain lung expansion and limit recurrence. While closed chest tube thoracostomy is offered as the main therapeutic approach in the majority of patients, emerging evidence suggests that this method may be relatively ineffective in limiting repeated pneumothoraces. Continued investigation focuses on the identification of variables that should prompt more aggressive therapy as well as the proper timing for various surgical interventions.

Methods

All patients treated at the Humana Hospital-University of Louisville for spontaneous primary pneumothorax were identified by the computerized diagnosis retrieval system of the medical records department. With the approval of the University Human Studies Committee, a retrospective analysis of each medical record was conducted to determine patient demographics, side of pneumothorax, extent of collapse, therapeutic interventions, hospital course, morbidity and mortality, and presence of comorbid disease.

Patients were included for analysis only if the medical record contained a radiographic report that confirmed the occurrence of a pneumothorax on admission. The size of the pneumothorax assessed by the radiologist was used for data comparison. Patients were excluded from this study if the pneumothorax could be attributed to trauma, malignancy, or infection.

The Student's two sample t-test was used for comparison of group means and Pearson's Chi Square method was used for comparison of group proportions. A p value of less than 0.05 was considered statistically significant.

Results

The records of 108 consecutive patients with primary spontaneous pneumothorax were reviewed. There were 71 males and 37 females. The patients ranged in age from 15 to 77 years (mean age was 32 years). There was no significant difference in the mean age of the males (32.5 $\pm$ 14.9 years) and females (31.9 $\pm$ 14.5 years). There were 54 right sided pneumothoraces and 54 left sided pneumothoraces. No patient presented with simultaneous spontaneous bilateral lung collapse. The mean size of the pneumothoraces did not differ according to side of occurrence, nor when analyzed by patient gender. In 87% of the patients, the admission episode was the first diagnosed pneumothorax (Table 1).

Each patient was initially treated in the emergency department with insertion of a large bore

catheter. No technical difficulties were recorded during placement of the chest tubes. Each tube was immediately attached to approximately 20 cm of water wall suction. One patient developed radiographic and clinical evidence of reexpansion pulmonary edema.

Only four patients (3.7%) received chemical pleurodesis. Each received intrapleural instillation of tetracycline through the catheter.

Thirteen patients (12%) displayed incomplete expansion due to persistent air leak and required surgery. While the two groups did not differ significantly in age or size of pneumothorax on admission, females were more likely to receive operative intervention (8/37, 21.6%) than were male patients (5/71, 7%); a p value of 0.027. The reason for this significant difference was not apparent from this retrospective study.

Table 1. Demographics of 108 patients with spontoneous pneumothorox (meon value + SD).

	Male n = 71	Femole n = 37
Age in yeors	32.5 ± 14.9	31.9 ± 14.5
% Size of pneumothorax	44.1 ± 26.1	41.4 ± 24.3
Days hospitalized	7.7 ± 5.4	8.5 ± 5.2
Initial episode	62/71	32/37
Recurrence	9/71	5/37
Right side	40/71	14/37
Left side	31/71	23/37
Chest tube droinage only	64/71	27/37
Chemical Pleurodesis	2/71	2/37
Thoractomy	5/71	8/37

Discussion

Treatment strategy for spontaneous pneumothorax is directed at achieving immediate reexpansion of the collapsed lung and prevention of relapse. A therapeutic algorithm should be helpful and while several are proposed, there remains considerable debate about the timing and best form of therapy.[4]

The time honored method of chest reexpansion has been the insertion of a large chest tube by blunt dissection or by trocar. This method is essential for drainage of fluid or blood, but may not be required in all cases when air is the only substance that needs to be evacuated. Each patient in our study who was treated initially received a large bore catheter that was immediately attached to a pleurovac with negative wall suction.

The potential disadvantages of this treatment include discomfort, patient immobility, residual scar, potential for reexpansion pulmonary edema, and the need for hospitalization. The risk of injury to the lung or visceral pleural from blunt dissection or trocar insertion has been described, but its incidence could not be assessed in this restrospective analysis. No iatrogenic injury was suspected in this study. The 88% successful reexpansion rate by our thoracic service was better than the usually quoted 81% initial success rate of conservative treatment with tube thoracoscopy.[5]

The insertion of a small caliber polyvinylchloride chest catheter of 12 Fr size that is attached to a one way Heimlich flutter valve has been proved to be safe, efficient, and economical.[6] The potential advantages of this treatment include avoidance of reexpansion pulmonary edema, lack of the need for a pleurovac, increased mobility and outpatient management, a smaller puncture wound, and decreased expense.[7] The disadvantages include the potential for occlusion of the small tube by kinking or secretions.[8] None of our patients were treated in this fashion, although almost all of our iatrogenic pneumothoraces have fared well with this therapy.

Spontaneous pneumothorax has a significant recurrence rate when only conventional pleural drainage procedures are employed for lung reexpansion. For this reason, physicians have attempted combining chemical pleurodesis with pleural drainage. A number of agents have been employed with temporary success. Favorite agents for scarification vary among institutions. Until recently tetracycline was widely used, but is now no longer available.[9] Talcum powder, Bleomycin, Atabrine, D50W, nitrogen mustard, silver nitrate, and autologous blood are other effective agents with reported success rates of 85%.[10]

If successful, chemical pleurodesis results in a statistically significant reduction ($p < 0.05$) in early recurrence of ipsilateral pneumothorax. The process may cause mild to moderate pleural thickening that can be seen radiographically. When side-to-side diaphragmatic excursion is compared in patients who have undergone unilateral pleurodesis, the diaphragmatic excursion of the previously sclerosed side is significantly diminished.[11] This measurable reduction on the affected side, however, is not associated with any significant restriction in lung function.[12,13]

Unfortunately, none of the chemical attempts at pleural symphysis permits adequate treatment of the lung lesion, which is usually one or more apical subpleural cystic lesions. The resulting adhesions involve primarily the diaphragmatic and mediastinal pleura.[14] The incidence and magnitude of late recurrences in a chemically scarified group is often no different than in the population treated with conventional drainage alone.[15] The procedure is often painful and occasionally associated with other troublesome side effects. This may be one reason that only 3.7% of our patients were offered chemical pleurodesis.

In lieu of catheter pleurodesis, thoracoscopy with direct visualization has offered a considerable advance in treatment of spontaneous primary pneumothorax, particularly identification of blebs in the apices of the upper lobes. The thoracoscope is introduced through a small incision (1-1.5 cm) in the anterior axillary line of the fourth intercostal space. The introduction of the endoscope allows local treatment methods (coagulation, laser, pleurodesis) and allows the clinician to make appropriate decisions regarding the need for thoracotomy.[16]

Thoracoscopy is an invasive form of endoscopy that can be performed with local anesthesia making it an ideal alternative to operative intervention in patients with advanced age or those with an increased surgical risk. It is generally recommened for patients with recurrent spontaneous pneumothorax or patients with a persistent air leak after 3 days of suction therapy.

Most investigators acknowledge a small but real rate of recurrence with thoracoscopy and use it sparingly for bullae of large size. If the bleb can be radiologically detected, most would favor thoracotomy with pleurectomy.

If thoracoscopy is not available to aid in the decision for surgical intervention, computerized tomography offers an alternative. Both the number of blebs and a bleb score that is calculated from the number of blebs multiplied by a numeric value determined by the range of bleb sizes is useful in predicting the ultimate need for thoracostomy.[17] Yet another successful procedure for imaging blebs or bronchopleural fistula that require surgery is contrast pleurography where contrast media is introduced through the chest tube and defines the shape of the pleural surfaces, the anatomic relations of interlobular spaces, and the boundaries of blebs and bullae.[18]

Surgical approaches depend on the primary disease, rate of recurrence, and localization. Many clinicians recommend surgery at the first relapse of spontaneous pneumothorax because it is alleged that this policy reduces hospital stay by 37%[19] and virtually eliminates recurrences. The type of surgical procedure is individualized according to the underlying lung pathology. Most often, in our institution, resection of blebs with abrasion of the pleura by dry sponge was employed. There was no operative mortality during our study period.

As thoracoscopy was not routinely employed at our University hospital, it appeared that persistent air leak was the primary determinant of surgical intervention. Published recommendations suggest that surgery be considered if an air leak persists for longer than 3 days after the initial episode of spontaneous pneumothorax or if the patient has a recurrence on clamping of the chest tube, nonexpansion of the lung despite adequate drainage, and the presence of giant bullae. Because the study was retrospective, we were unable to always document which patients were offered surgery but may have refused. It is interesting to note that more female patients had operative intervention than males ($p < 0.027$), although males outnumbered the female patients 71/38.

The quality of life after surgical approach is almost always satisfactory. The chief complaint has been that of post-thoracotomy pain (13%) and disturbance of sensation in the scar (10%). However, only 4% of patients have any difficulty with the activities of daily life. Recurrence rate is less than 1%.[20]

In summary, we offer a descriptive account of the management of 108 consecutive cases of primary spontaneous pneumothorax at a teaching hospital. We propose that it will serve as a baseline for comparison for a similar analysis of the next 5 years of care for this problem now that thoracoscopy and small catheter air drainage with a one-way Heimlich valve have become more accessible. Each of these procedures may offer a more cost effective alternative to current conventional therapy.

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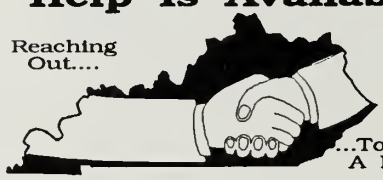
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Rights

The tidal wave of health care reform has swept along with it an ever-growing collection of "rights." We have seen and heard the litany of a citizen's right to health care, a patient's right to choose a physician, a patient's right to die, a physician's right to practice medicine as they see fit . . . the list goes on. In this discussion, the concept of responsibility attendant to these rights is rarely discussed. Yet, as in perhaps no other aspect of our lives, our personal and societal health should provoke a clear and open consideration of our individual rights and responsibilities. Still, the examples of individuals and of our society expecting the bestowal of rights without responsibility seem to outstrip the contrary all too often.

Recently, the Veteran's Administration decided to provide Agent Orange benefits to any Vietnam veteran with lung cancer regardless of the ability to firmly document exposure and in the face of scanty medical evidence at best. A recipient with a 35-year smoking history and an administration official interviewed see no problem with the disparity . . .

A patient recently related a situation in which her company changed to a new insurance program. She was informed by her doctor's office that they had decided to withdraw their participation from the patient's insurance program. The patient, in the face of significant economic hardship, opted to pay her physician of 15 years out of pocket rather than switch at age 62 to a participating physician . . .

"As in perhaps no other aspect of our lives, our personal and societal health should provoke a clear and open consideration of our individual rights and responsibilities."

A patient recently was informed by his physician that he had developed an end-stage cardiomyopathy from chronic alcohol abuse. The angry patient and even angrier family berated the physician for not adequately monitoring the patient and for not intervening sooner despite multiple unsuccessful physician-initiated trips through rehab programs . . .

If the current debate over the reform of our health care system is to be ultimately successful, we must as a society come to a consensus on what we will expect from each other in return for the myriad promises being made on every citizen's behalf in the overhauled health care system. We do this in virtually every other facet of lives: the defense of the country, the funding of government programs, safe transport on roads and in the air. When considering our own health and the health of our society, we should do no less.

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143RD KMA ANNUAL





Top: The first woman President of KMA, Ardis D. Hoven, MD, is pictured with, L to R, Secretary-Treasurer William P. VonderHaar, MD, President-Elect Robert R. Goodin, MD, and Vice President William H. Mitchell, MD. Left: KMA Past President Preston P. Nunnelley, MD, accepted an Educational Achievement Award on behalf of his OB-GYN colleague, W. David Hager, MD, of Lexington. Right: President Hoven shares in the excitement of the other Educational Achievement Award honorees, H. David Wilson, MD, Lexington (L), and Larry P. Griffin, MD, Louisville.







MEETING





Top left: President-Elect Robert R. Goodin, MD, was escorted to the podium by Past Presidents Wally O. Montgomery, MD (L), and Bob M. DeWeese, MD. Right: President Hoven is pictured with KMA Executive Vice President Robert G. Cox. Center: Immediate Past President William B. Monnig, MD, addressed the House of Delegates. Bottom left: Donald C. Barton, MD, Corbin, was honored with KMA's highest award, the Distinguished Service Award. Awards Chairman Nelson B. Rue, MD (R), made the presentation. Right: Board Chairman Russell L. Travis, MD, administered the presidential oath to Dr Hoven.





Top: State Senator Nick Kafoglis, MD, chatted with Dr Hoven prior to addressing the KEMPAC assembly. Center: Dr Rue presented the KMA Award to Cecil Dulin Wallace. Bottom: The KMA MSS/RPS Annual Meeting was highlighted by a panel discussion. Panelists were (L to R) AMA Delegate and KMA President-Elect Robert R. Goodin, MD; KMA Public Affairs Director Don Chasteen; Scott Black, MD, a Barbourville family physician; UKMC Associate Dean H. David Wilson, MD; and narrator Judy Linger, MD, an AMA-RPS Governing Council member.



Inauguration

Ardis D. Hoven, MD, a Lexington infectious disease specialist, was inaugurated 1993-94 President of KMA at the 143rd Annual Meeting held in Louisville, September 27-30. Dr Hoven is the first woman President in the history of the Association. A graduate of the University of Kentucky College of Medicine, Dr Hoven has served as Alternate Delegate to the AMA since 1989, and in 1991 served as Vice President of KMA. She is Immediate Past Chairperson of the Fayette County Board of Health and serves on the Governor's AIDS Policy Advisory Council. In 1991, Dr Hoven received the KMA Educational Achievement Award for outstanding contribution in the field of medical education.

Elections

Robert R. Goodin, MD, a Louisville cardiologist, was elected to the office of President-Elect. A graduate of the University of Louisville School of Medicine, Dr Goodin is a past president of the Jefferson County Medical Society. From 1986 until 1990 he served as a KMA Alternate Delegate to the AMA House of Delegates, and has served as a KMA Delegate to the AMA since 1991. Dr Goodin has chaired several KMA committees including Changing Trends in Medicine and Faculty Practice, and currently chairs the Physician Manpower Committee and is a member of the Continuing Medical Education Advisory Committee. This year he became a member of the AMA Continuing Medical Education Advisory Committee.

William H. Mitchell, MD, a Richmond surgeon, was elected to the office of Vice President. Dr Mitchell is a past president of the Madison County Medical Society, has been a KMA Trustee since 1986, and has

served on the KMA Executive Committee since 1990. He is a consultant to the Kentucky Board of Medical Licensure and a physician advisor for the state PEER Review Organization and the Physician Manpower Committee. A graduate of Johns Hopkins University, Dr Mitchell is immediate past president of the Kentucky Chapter of the American College of Surgeons, Hiram C. Polk Surgical Society, and is a member of the clinical faculty at the University of Kentucky and the University of Louisville.

Two new Trustees were elected: Timothy K. Hulsey, MD, Bowling Green, 6th District; and G. Irene Minor, MD, Berea, 11th District.

The Board elected the Executive Committee members to serve with the President, President-Elect, Vice President, and Secretary-Treasurer for the 1993-94 KMA year. Don R. Stephens, MD, was elected Chair, Board of Trustees, and John W. McClellan, MD, Henderson, was reelected Vice Chair. Harry W. Carloss, MD, Paducah, and Russell L. Travis, MD, Lexington, were named as Trustees-at-large.

Five physicians were elected by the House of Delegates to serve on the 1993 Nominating Committee. Members elected were:

James E. Redmon, MD
Louisville, Chair
Donald E. Brown, MD
Somerset
Ralph L. Cash, Jr
Princeton
W. Lisle Dalton, MD
Lexington
Susan H. Prasher, MD
Ashland

President's Luncheon

The President's Luncheon guests honored outgoing President William B. Monnig, MD, and witnessed the installation of Ardis D. Hoven, MD, as the 143rd President of KMA.







Top: Dorothy Hoven, mother of President Hoven, shared in the excitement of her daughter's achievement. Center: AMA Trustee Randolph Smoak, MD, addressed the House of Delegates. House Speaker Danny M. Clark, MD, Somerset, and Vice Speaker C. Kenneth Peters, MD, Louisville, are pictured in the background. Bottom: Secretary-Treasurer William P. VonderHaar, MD, shared a light moment with other Board members.







Top: 11th District Trustee G. Irene Minor, MD, chatted with 4th District Trustee Salem M. George, MD. Center: An outstanding group of guest speakers addressed a near capacity crowd in the General Sessions hall. Bottom: Dr Carl C. Cooper studied the program book while relaxing in the spacious, attractive lounge area of the Exhibit Hall.

In her Inaugural Address, Dr Hoven focused on KMA's commitment to meaningful health systems reform. Notable comments included, "I would suggest to you two measuring sticks or instruments by which we may evaluate and judge the elements being considered in the reform process: advocacy for patients and advocacy for the profession of medicine. If the policies and procedures being considered do not meet our standards in these two areas, we must both candidly and in the spirit of cooperation speak out. . . . Never before has the issue of unity among physicians and organized medicine been so important as it is now. There is simply no room for polarization or fragmentation. The problem solving skills we all possess, our abilities to communicate with one another and our dedication to a very high and special calling should enable us cohesively and confidently to move forward. . . . As the first woman to hold this position, I am greatly honored and challenged to work diligently and effectively on your behalf." Dr Hoven's address is printed in its entirety in the October 1993 *Journal.*

DSA Award

The Association's most prestigious honor, the Distinguished Service Award, was bestowed upon Donald C. Barton, MD, a Corbin family practitioner. He was honored at the President's Luncheon for not only his contributions to the profession but also to his community.

Dr Barton, a Diplomate of the American Board of Family Practice, has served on the KMA Board of Trustees in various elected offices since 1978. During a 6-year term as KMA Trustee, Dr Barton served one term as Vice Chairman and two terms as Chairman of the Board of Trustees. In 1985, he was elected KMA Vice President, in 1986, President-Elect, and in 1987 assumed the office of President of KMA, where he served with great honor and respect. In 1983, he was elected AMA Alternate Delegate and in 1984 was elected by the KMA House of Delegates as a Delegate to AMA, a position he still holds. He is the senior Kentucky Delegate to the AMA and Chairman of

KEMPAC Dinner attendees had an opportunity to meet with several of the state's most influential leaders. Included were (top photo) State Representative and KMA Past President Bob M. Deweese, MD, and his wife Angie; (center L to R) Mike Ward, State Representative from Louisville and candidate for 3rd Congressional Representative, chatted with State Senator Walter Baker of Glasgow. Fay Neel, Alliance Representative for the KEMPAC Board, was seated with State Representative Lewis Johnson; (bottom L to R) State Senator Susan Johns took a few seconds to be photographed, and Senator Baker shared a table with KMA President-Elect Robert R. Goodin, MD, and Susan Stokes, candidate for the 3rd Congressional seat.

the Kentucky Caucus. Dr Barton has been active on the local level where he served as President of his County Medical Society, and on the Board of Directors and Chief of Staff of the Baptist Regional Medical Center in Corbin. He was deeply involved in KMA's decision to form the Kentucky Medical Insurance Company and has served on the KMIC Board of Directors since 1991.

In his presentation of the award to Dr Barton, Nelson B. Rue, MD, Chairman of the Awards Committee, included these comments:

"Dr Barton has a long history of political involvement, both within medicine and outside of medicine. He has been *the* most formidable















Top: Susan H. Prasher, MD, and Kenneth R. Hauswald, MD, Delegates from Ashland, discussed the proceedings with (R) 13th District Trustee Charles T. Watson, MD. Center: Delegates Thomas M. Gadient, MD, Henderson, and Beverly M. Gaines, MD, Louisville, relaxed during a break in House actions. Bottom: G. Randolph Schrodt, Jr, MD, listened intently to his father G. Randolph Schrodt, MD. Both were Jefferson County Delegates.



physician activist in the state of Kentucky. Our honoree is one of those rare physicians who, as politicians like to say, 'puts his money where his mouth is.' He has been extremely up front helping out budding young politicians who share his philosophy and who need financial assistance to run political campaigns on the local, state, and national levels. Many legislators have remarked that Dr Don came to them either before or right after they first announced for a political office and offered his personal and financial support. He was an early proponent of KEMPAC, the political arm of KMA. He served on that Board from 1971 to 1977, two terms as Chairman. As Chairman of KMA's National Legislative Committee, he has remained on the KEMPAC Board where he has served for 22 unselfish years. Dr Barton is a Key Contact physician for several state legislators and Congressmen. He was appointed by President George Bush to serve on the National Medical Advisory Committee and Governor Brereton Jones nominated him to the Governor's Task Force on Health Care Access and Affordability. In addition to these high-profile posts, he was appointed by the Governor to the State Health Services Advisory Council and received an appointment as Chairman of the Family Planning Task Force Committee. Our recipient has been a member of the Kentucky Health Care Access Committee since its inception. As you can see, our honoree is respected by leaders of both political parties.

"From 1969 through 1975, Dr Barton served on the Corbin City Council and was Mayor Pro Tem of Corbin during those years. He has also been delegate to the Republican National Convention, a highly coveted and powerful position, in 1984, 1988, and 1992.

"Our honoree had a distinguished military career as a United States Army Captain. In 1968

he was company commander in the 1st Air Calvary Division in Viet Nam and was awarded the Bronze Star.

"In 1966 the city of Corbin awarded Dr Barton the Distinguished Service Award. He is also recipient of the Citizen Doctor of the Year Award, given by the Kentucky Academy of Family Practice, the highest honor a specialty group gives to a member. By honoring him today we echo those who have recognized a man with enormous qualities and integrity. But despite all these awards and accolades, to the man on the Corbin street, he's just plain Dr Don, who has always taken care of his people regardless of their station in life — regardless of their ability to pay.

"Albert Einstein once said, 'A person first starts to live when he or she lives outside themselves.' Abraham Lincoln offered similar advice, which our nominee must have read, when he noted that 'You cannot help men permanently by doing for them what they must and should do for themselves.' By his deeds and actions, Don Barton has 'lived outside himself.' He has very quietly, but very effectively, used his talents, good humor, and integrity, to truly effect the forces of change. For this we owe him a deep sense of gratitude."

Lay Person Award

The KMA Award, which is awarded to a lay person who has made significant contributions to the medical community, was presented to Cecil Dulin Wallace, and posthumously to her husband Joe A. Wallace.

The late Joe A. Wallace was a native of Shelby County, graduated from Centre College and the Jefferson School of Law. Mr Wallace was a member and Chairman of the Board of Directors of Home Mutual Insurance company. He was a very strong and successful business person who had many close ties to the medical community.

Cecil Dulin Wallace, wife of Joe, is a native of Boyle County, attended Centre College, and graduated from Mt. Holyoke College in Massachusetts. Cecil Dulin Wallace has been extremely active on the local, state, and national levels in preserving historical sites and landmark buildings. She played a leadership role in the preservation of Perryville Battleground and various other central Kentucky landmarks. She has been extremely involved in the Ephraim McDowell House and its restoration and maintenance. The





Top: KMIC Board Chairman Richard F. Hench, MD, addressed the House. Center: KMAA Past President Beryl Dodds congratulated Dr H. David Wilson on receiving an Educational Achievement Award. Bottom: Board Chairman Russell L. Travis, MD, Lexington, reviewed the House agenda with Fayette County Delegates William D. Medina, MD (L), and James R. Bean, MD (R).



summer home and farm of Dr Ephraim McDowell has been in Cecil Dulin Wallace's family since 1858 and is known as the Cambus-Kenneth Farm.

Awards Chairman Rue expressed his gratitude and that of the Association as he concluded the presentation.

"Several years ago, the Wallaces decided to preserve the Cambus-Kenneth Farm, Dr McDowell's summer home, and its buildings and grounds for all future generations. In 1988, the Wallaces asked the Kentucky Medical Association to establish a special Cambus-Kenneth Foundation, a non-profit group which would eventually be responsible for preserving and maintaining this historic landmark and legacy in accordance with the wishes of Joe A. and Cecil Dulin Wallace. This foundation, once finalized, will for all times be guardian of the property of McDowell and preserve it for future generations of Kentuckians and the world. The legacy of Dr Ephraim McDowell of Danville, whose home in downtown Danville is presently owned and operated by the KMA, will once again, and hopefully forever, be brought under one umbrella. While there are many kind things that we could say about Joe and Duley Wallace, particularly their regard for their community, state, and nation, more particularly, it is their concern for people and those who follow who will truly benefit from their lives and contributions."

Educational Achievement Award

Three extremely qualified physicians were selected by the CME Committee to receive Educational Achievement Awards this year. The Committee revised the criteria for the award last year and received numerous nominees for the award, which resulted in the decision to name the following three honorees:

W. David Hager, MD, a practicing OB/GYN from Lexington who also serves as professor at the University of Kentucky College of Medicine, Department of Obstetrics and Gynecology, was named a recipient. Dr Hager is the Director of Residency Training at Central Baptist Hospital for the UK Department of OB/GYN and a member of the American College of Obstetrics and Gynecologists Course Coordination Committee, which plans and develops all continuing medical education courses for this organization. He has authored two books, "Infection Protocols in OB/GYN," published in November 1992, and "Women at Risk and the Men in Their Lives," published in January 1993. Dr Hager participates on an ongoing basis in lectures and seminars at both the Annual Clinical Meeting and the Annual District Meeting of District V of the American College of Obstetricians and Gynecologists. Dr Hager could not be present at the awards ceremony, and Preston P. Nunnelley, MD, a fellow Lexington OB/GYN, accepted the award on behalf of Dr Hager.

H. David Wilson, MD, a faculty member of the University of Kentucky College of Medicine since 1967, was also a recipient. Dr Wilson is board certified in pediatrics and infectious disease, and has demonstrated excellence in education as a clinician, teacher, and administrator. He is actively involved in clinical education of students and residents and is a frequent consultant to physicians throughout Kentucky. Since 1989, he has served as Associate Dean for Academic Affairs, where his primary responsibilities have been curriculum development. Dr Wilson was primarily responsible for the selection of the University of Kentucky as one of only eight medical schools for funding by the Robert Wood Johnson Foundation to restructure the medical curriculum. As a result, the UK College of Medicine can have a major impact on medical education in this country. His administrative skills effectively developed the new curriculum and confirmed faculty approval. Dr Wilson is now in the process of implementing the new curriculum in a highly successful manner.

Larry P. Griffin, MD, the immediate past Chairman of the CME Committee, was also named. Dr Griffin has served as the Director, Residency Program in Obstetrics and Gynecology, St. Vincent Hospital and Health Care Center, since 1989; Associate Clinical Professor, Department of OB/GYN, Indiana University College of Medicine, since 1989; Assistant Clinical Professor, Department of OB/GYN, University of Louisville, since 1981; and Clinical Instructor, Department of OB/GYN, University of Kentucky College of Medicine, since 1987. Additionally, Dr Griffin was a participant in the Harvard School of Public Health Resource Based Relative Value Scale Study as a Technical Consultant from 1986-89.

Scientific Exhibit Award

Several excellent Scientific Exhibits were displayed at the 143rd KMA Annual Meeting. The award winner was an outstanding presentation by John J. Guarnaschelli, MD, David A. Petruska, MD, and Freida Manion, RN, entitled "Brain Tumors in Adults: A 20 Year Experience of 1010 Operative Cases."

Forum on Health Care Reform

During the Monday House of Delegates, President William B. Monnig, MD, presided over a special session on health care reform. The session was open to all members.

Alliance AMA-ERF

During the first meeting of the House of Delegates, Beryl Dodds, KMAA Past President, presented AMA-EFR checks to the two medical schools on behalf

of the Alliance. Since 1950, the AMA-ERF has continually been supportive of quality medical education, with contributions now exceeding $2 million annually. The extraordinary fund raising efforts of the AMA Alliance and the generosity of contributing medical families and private enterprise continue to secure AMA-ERF as a viable support for medical education.

In Kentucky, AMA-ERF funds are given proportionally to the two medical schools as designated by the donors. Donald R. Kmetz, MD, Dean of the University of Louisville School of Medicine, accepted a check from Mrs Dodds for $26,585.33 and Emery A. Wilson, MD, Dean of the University of Kentucky College of Medicine, accepted a check for $20,448.21.





Left: KMA Alliance President Gloria Griffin, Louisville, proudly holds the Educational Achievement Award received by her husband Larry P. Griffin, MD. Below: The KMA Alliance held their Fall Board Meeting in conjunction wih the KMA Annual Meeting. President-Elect Joyce Clark, Somerset, addressed the assembly while Recording Secretary Marna Loucks, President Gloria Griffin, and Parliamentarian Ruth Ryan took notes.

Fifty-Year Members

Those KMA member physicians who have been practicing medicine for 50 years or more were recognized during the President's Luncheon. Achieving that status this year are: Drs Louis E. Aaron, Lundy Adams, Edward T. Arnn, L. Douglas Atherton, Edward E. Bell, Thomson R. Bryant, Jr, Clarence E. Claugus, Walter S. Coe, Patrick W. Cummings, Mary Long Davis, Rudy J. Ellis, Merle W. Fowler, David W. Griffin, Francis J. Halcomb, Phil J. Harbrecht, Charles R. Hoffman, William E. Hoy, Jr, Karl C. Kelty, Esten S. Kimbel, Blaine Lewis, Jr, Conie C. Lowry, Wendell V. Lyon, Eugene L. Marion, Thomas R. Miller, David Nelson, Earl P. Oliver, Gabe A. Payne, Clarence E. Quaife, Rogers L. Queen, Mack Rayburn, Benjamin F. Roach, Irvin S. Rosenbaum, Saul Rubin, Fred A. Sawhill, Everett W. Schaeffer, Arthur M. Schoen, Melvin Shein, George C. Sivak, Enos T. Smith, Richard C. Spear, Robert R. Starr, Elliott P. Stevens, William J. Temple, Kearns R. Thompson, T. C. Van Arsdall, Sr, Carl A. Waldemayer, Roy G. Wilson.

In Memoriam

During the first House of Delegates meeting, Secretary-Treasurer William P. VonderHaar, MD, requested that the audience stand for a moment of silence in memory of those physician members who had died in the last year. A list of the deceased appears on page 539 of this *Journal.*

KMA-MSS and RPS

Approximately 100 medical students and residents attended the 1993 KMA MSS/RPS Annual Meeting held on September 28 and expressed a great deal of interest in the panel discussion on "Changing Dimensions of Medicine" as evidenced by a lengthy question and answer session.

Panelists and topics were: KMA Public Affairs Director Don Chasteen (Legislative Arena); Scott Black, MD, Barbourville family physician (Financing a Medical Career); UKMC Associate Dean H. David Wilson, MD (Choosing Primary Care vs Specialty); and Robert R. Goodin, MD, AMA Delegate and KMA President-Elect (Managed Competition).

In addition, Ardis Hoven, MD, encouraged the group to stay involved in the activities of organized medicine, and AMA-RPS Governing Council member, Judy Linger, MD, reported on the current legislative issues at the national level affecting students and residents.

KEMPAC

The 31st KEMPAC Seminar Banquet was held during this year's Annual Meeting on Monday, September 27, at the Hyatt Regency Hotel, Louisville. A large audience of physicians, spouses, Kentucky State Representatives, Senators, and their staff were addressed by State Senator Nick Kafoglis, MD, and State Representative Bob M. DeWeese, MD. Samuel Jerry King, MD, Pikeville, KEMPAC Chairman, presided at the meeting.

House Action Summary

The 1993 KMA House of Delegates adjourned on September 29, 1993, after making some important decisions on a number of health care issues. The evening was highlighted with a message to the Delegates from AMA Trustee Randolph Smoak, Jr, MD, who expressed the position of the AMA on the proposed Clinton Health Care Reform plan. Dr Smoak stressed that all physicians should become involved in the political process by contacting their elected officials and discussing health care reform with them. A summary of the President's plan which included the AMA response to the plan was distributed to all Delegates. The summary was previously mailed to all physicians in the United States.

Included in the AMA summary is an information section for patients. On behalf of Dr Smoak, the House of Delegates encourages all physicians in Kentucky to make this information available to, and discuss it with, their patients. Refer to the November issue of the *Journal* for a related special article.

Highlights of actions taken by the House are listed below. Please refer to the House of Delegates section in this *Journal* for a complete text of the Committee Reports and Resolutions.

- Called upon the KMA Board of Trustees to initiate a study of the feasibility of establishing a physician owned and directed economic entity to allow all KMA members the opportunity to participate in delivery and payment systems evolving from state and national health system reform measures. In conducting the study, the Board of Trustees will consider legal, professional, and financial requirements and may engage the services of a consultant to assist in the process.
- Recommended KMA continue to support the practice of physicians and physician assistants in which PAs are supervised by licensed physicians; to endorse legislation that allows licensed physicians who are approved to supervise physician assistants and the authority to delegate to PAs in their practice the prescribing, dispensing, and ordering of nonscheduled medications in accordance with the oversight of the supervising physician.
- Directed KMA to urge Kentucky's medical schools to adapt their curriculum to include training for domestic violence cases including recognizing and reporting abuse, proper techniques for interviewing and diagnosing patients, and proper documentation of abuse of the patient.
- Encouraged the KMA to ask the KMA Hospital Medical Staff Section to work with the KMA Resident Physicians Section in addressing the goal of establishing resident medical staffs in all Kentucky training hospitals.
- Directed KMA to work with the insurance community to develop an efficient mechanism for communication between the medical profession and the insurance industry at the state level.
- Recommended that the KMA address the issue of the limited supply of extended care beds in Kentucky and recommend to the Legislative Committee action to bring about resolution of this problem and to devise a master plan to address this issue in the '90s and communicate the plan to the General Assembly for action.
- Opposed the use of shifting Medicaid funds to balance the general budget and directed KMA to pursue remedies to overturn the provider tax and work to defeat rate setting and global budgets.
- Directed the KMA to have the Committee on Medical Insurance and Prepayment Plans collect guidelines on the appropriate use of physicians as assistants at surgery already developed by medical specialty societies and have the Committee report the results to the Board of Trustees with recommendations on how the information may best be utilized.
- Urged KMA to contact Kentucky's Congressional Delegation in the event that an incinerator is built in Madison County to destroy chemical weapons stored at the Bluegrass Army Depot and encourage the Delegation to limit the use of the incinerator to destruction of current on-site nerve agent and mustard agent, and vigorously oppose using Bluegrass Army Depot as a national or regional toxic waste disposal facility.
- Expressed sincere thanks to William

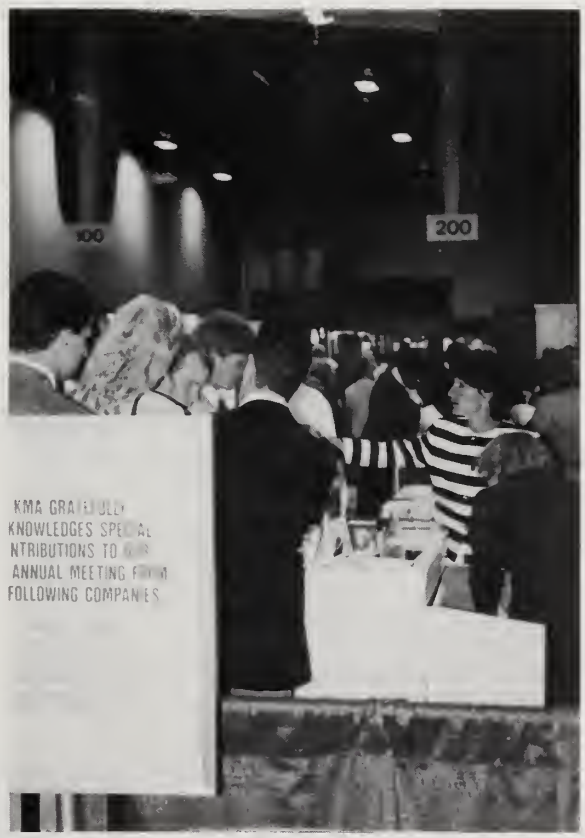
B. Monnig, MD, for his major role over the past year as President and his devotion to health care reform activities, as well as his commitment to KMA for more than 17 years.

- Accepted the report of the Membership Committee which noted that KMA active membership has now surpassed 4,000 members for the first time in its history.
- Recommended KMA strongly support the patient's freedom of choice of physician and support and encourage a pluralistic approach to health care delivery that allows patients the option of choosing their own physician.
- Urged the KMA to contact insurance carriers and encourage them to process claims submitted nonelectronically routinely, without unnecessary delay.

Attendance

This year's KMA meeting attracted a record-breaking crowd of 2,630. Physicians numbered 1,159 and medical students 326, resulting in a very successful 143rd KMA Annual Meeting at the Hyatt Regency Hotel/ Commonwealth Convention Center in downtown Louisville. The 1994 Annual Meeting will also be held in Louisville. The Board of Trustees has again selected the very accommodating and spacious Hyatt Regency Hotel/Commonwealth Convention Center to house the meeting. Over 22 specialty groups and an estimated 2800 registrants are expected to attend.

Please mark your calendars to attend the 1993 KMA Annual Meeting to be held September 19-22.



KMA extends a special thanks to the 125 Technical Exhibitors who displayed at this year's annual meeting. Their participation is invaluable to the success of the KMA Annual Meetings.

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ROLL CALL
1993 House of Delegates
KMA Annual Meeting

OFFICERS

		First Meeting	Second Meeting
Speaker	Donny M. Clork	Present	Present
Vice Speaker	C. Kenneth Peters	Present	Present
President	William B. Monnig	Present	Present
President-Elect	Ardis D. Hoven	Present	Present
Vice-President	David C. Liebschutz	Present	Present
Secretory-Treasurer	Williom P. VonderHoor	Present	Present
Delegote to the AMA	Donold C. Borton	Present	Present
Delegote to the AMA	Horold L. Bushey	Present	Present
Delegote to the AMA	Robert R. Goodin	Present	Present
Delegote to the AMA	Wolly O. Montgomery	Present	Present
Alternote Delegote to the AMA	J. Gregory Cooper	Present	Present
Alternote Delegote to the AMA	Bob M. DeWeese		Present
Alternote Delegote to the AMA	Ardis D. Hoven	Present	Present
Alternote Delegote to the AMA	Donold J. Swikert		Present

TRUSTEES

District			
First	Horry W. Corloss	Present	
Second	John W. McClellon, Jr	Present	Present
Third	Williom H. Klompus	Present	Present
Fourth	Solem M. Georgе		Present
Fifth	Joseph E. Kutz	Present	Present
Sixth	Jerry W. Mortin	Present	Present
Seventh	Ronold L. Woldridge	Present	
Eighth	Mork F. Pelstring	Present	Present
Ninth	Donold R. Stephens	Present	Present
Tenth	Russell L. Trovis	Present	Present
Eleventh	Williom H. Mitchell	Present	Present
Twelfth	Scott B. Scutchfield	Present	Present
Thirteenth	Chorles T. Wotson	Present	Present
Fourteenth	Elster D. Roberts	Present	Present
Fifteenth	Poul R. Smith	Present	Present

ALTERNATE TRUSTEES

District			
First	Don M. Miller	Present	
Second	Christopher R. McCoy		
Third	Chorles R. Dodds		
Fourth			
Fifth	Lorry J. Wilson	Present	Present
Sixth	John D. Gover		
Seventh	John Michoel Wotts		
Eighth	John D. Ammon		
Ninth	Robert L. McKenney	Present	Present
Tenth	Gory R. Wolloce		Present
Eleventh	G. Irene Minor	Present	Present
Twelfth	Donold E. Brown	Present	Present
Thirteenth	Bruce M. Stopleton		Present
Fourteenth	Vivente B. Sontelices		
Fifteenth	Rogelio A. Acosto		Present

PAST PRESIDENTS

Post President	S. Rondolph Scheen	Present	Present
Post President	Preston P. Nunnelley	Present	Present
Post President	Nelson B. Rue	Present	Present
Post President	Bob M. DeWeese		Present
Post President	Donold C. Borton	Present	Present

DELEGATES
FIRST DISTRICT

		First Meeting	Second Meeting
BALLARD			
CALLOWAY	R. Gory Morquordt	Present	Present
	Don Miller	Present	
CARLISLE	Glenn E. Hogoncomp	Present	
FULTON			
GRAVES	Chorles E. Bea	Present	Present
	Thomos G. Russell, Jr		
HICKMAN	Bruce C. Smith		
LIVINGSTON	Stephen Burkhort		
MARSHALL	H. W. Ford		
MCCRACKEN	Horry W. Corloss	Present	
	Keith H. Crowford		
	Chorles K. Davis		
	Lorry C. Fronks		Present
	Stephonie R. Hotfield		
	John D. Noonon	Present	Present

SECOND DISTRICT

DAVIESS	Jock C. Blockstone, Jr	Present	Present
	Gerold G. Edds	Present	Present
	Williom C. Horrison	Present	Present
	Christopher J. Haveldo		Present
	Philip B. Hurley	Present	Present
	R. Wothen Medley, Jr		Present
	Williom L. Tyler, III	Present	Present
HANCOCK	Dovid K. L. Ton		
HENDERSON	Thomos M. Godient	Present	Present
	Fronk K. Sewell, Jr	Present	
	Rogelio A. Silvo	Present	
MCLEAN			
OHIO			
UNION	Wollos N. Bell	Present	Present
WEBSTER			

THIRD DISTRICT

CALDWELL	Rolph L. Cosh, Jr		
CHRISTIAN	Emmonuol J. Battoh		
	Horry J. Dempsey		
	J. Nicholos Terhune		
CRITTENDEN			
HOPKINS	Wolloce R. Alexonder	Present	Present
	Udoykont V. Dove	Present	Present
	Cynthio Horbough	Present	Present
	Mohon K. Roo	Present	Present
	Rodger J. Zwemer	Present	Present
LYON	Steve Hilond		
MUHLENBERG	Jomes S. Brosheor		
TODD	Honk Bell, Jr		
TRIGG			

FOURTH DISTRICT

BRECKINRIDGE	Jomes G. Sills		Present
BULLITT			
GRAYSON	Roy A. Cove	Present	
GREEN			
HARDIN-LARUE	Vivion H. Blond	Present	Present
	Dovid Anh Duy Doo		Present
	Amorjit M. Desoi		Present
	Lucion Yonn Moreman, II	Present	Present
	Jeffrey B. Richordson	Present	Present
HART	Georgе B. Boeckmonn		

MARION	Frederick A. Darrah		
MEADE	Raymand L. Mathis	Present	Present
NELSON			
TAYLOR	Eugene H. Shively	Present	Present
WASHINGTON	Suk K. Kah		Present

FIFTH DISTRICT

JEFFERSON	Jannice O. Aaran		
	Arnald M. Belker		Present
	Susan M. Berberich		Present
	Charles J. Bisig, Jr	Present	Present
	David H. Bizat		Present
	Harald W. Blevins		Present
	Susan G. Bornstein		Present
	Mark H. Branner		
	William C. Buschemeyer, Jr	Present	Present
	David E. Bybee	Present	Present
	Peter C. Campbell		Present
	Stuart P. Cahen		
	J. William Camer		
	Peter M. Canway		
	Warren M. Cax, IV		Present
	Jahn H. Dayle	Present	Present
	Rudy J. Ellis, Jr		Present
	Jahn M. Farmer		
	Marjarie R. Fitzgerald		Present
	Larry D. Flarman		
	Beverly M. Gaines		Present
	Hayt Gardner		Present
	Katherine P. Garrisan		Present
	Julius T. Gavin		Present
	Darius Ghazi	Present	Present
	Eugene Giles		Present
	Linda Gleis		Present
	Harald D. Haller	Present	Present
	B. Thomas Harter, Jr	Present	Present
	Peter Hasselbacher		Present
	Walter I. Hume, Jr	Present	Present
	Barbara Sue Isaacs		Present
	Clifford V. Jennings		Present
	Jahn Jurige, Jr		Present
	Sheri A. Kalfleisch		Present
	Jahn M. Kariba	Present	Present
	Danald R. Kmetz	Present	Present
	Russell T. May		
	Martha T. McCay		Present
	Garden T. McMurry	Present	Present
	Rabert L. McQuady, Jr.	Present	Present
	Frank B. Miller		
	Catherine Newtan		
	Rabert L. Nald	Present	Present
	Vaughn W. Payne		Present
	Habert L. Pence		Present
	Hugh R. Petersan, Jr.	Present	Present
	Steve J. Raible		Present
	James E. Redman	Present	Present
	K. Thamas Reichard	Present	Present
	William M. Renda		Present
	George R. Schrodt		Present
	George R. Schrodt, Jr.		Present
	Edward L. Scafield	Present	Present
	Kerry L. Shart		
	Lynn T. Siman	Present	Present
	Judah L. Skalnick		Present
	Wm. C. Templetan III		Present
	Rebecca Terry		
	Alfred L. Thampsan		Present
	Stuart Urbach		Present
	Daniel W. Varga		Present
	Gary C. Vitale		
	Nartan Waterman		Present
	David R. Watkins		
	Samuel D. Weakley		Present
	Barbara Weakley-Janes	Present	Present
	A. Franklin White, Jr	Present	Present
	Jahn J. Whitt		Present
	Russell A. Williams		Present
	C. Miltan Yaung, III	Present	Present

SIXTH DISTRICT

ADAIR	Richard Lenaghan		Present
ALLEN	Earl P. Oliver	Present	
BARREN	Ray A. Gibsan		
	Marris David Mass		
BUTLER			
CUMBERLAND	Joseph D. Skipwarth		Present
EDMONSON	Omkar N. Bhatt		
LOGAN	William Albert		Present
METCALFE	Lawrence P. Embertan		
MONROE	James E. Carter		
SIMPSON	Michael Pulliam	Present	Present
WARREN	James F. Beattie, Jr	Present	Present
	Jahn T. Burch	Present	Present
	Jae T. Davis	Present	Present
	Stuart G. Yeaman		Present

SEVENTH DISTRICT

ANDERSON	Patrick A. Sheridan	Present	Present
CARROLL	Frank F. Palmer	Present	Present
FRANKLIN	Jahn M. Pattersan		Present
	Jeffrey L. Rice		
	Jan J. Weisberg		Present
GALLATIN	Benjamin Kutnicki	Present	Present
GRANT			
HENRY	Steven D. White		
OLDHAM	Harald F. Funke		Present
OWEN	O. Abbett Cull		
SHELBY	M. Brooks Jackson, II	Present	
SPENCER	Thamas C. Crain		
TRIMBLE	Roderick H. MacGregar		

EIGHTH DISTRICT

BOONE	Robert L. Baker, Jr		
	David S. Rass		Present
CAMPBELL	Tood M. Cook		
	James Evans, III		
	Frederick Stine	Present	Present
KENTON	Gardan W. Air		Present
	Jahn Franklin Allnutt		
	Elbert D. Baldridge, Jr	Present	Present
	Thomas E. Bunnell	Present	Present
	Daniel G. Fagel		Present
	Joseph C. Martin		Present
	Rass McHenry		
	Caral S. Milburn		Present
	Theodare H. Miller	Present	Present
	Mary Redden Barawski		Present
	Marguerite S. Schabell	Present	Present
	B. Rabert Schwartz	Present	Present

NINTH DISTRICT

BATH	Rabin A. Byran		

BOURBON	Emmett Lee Tote		
BRACKEN			
FLEMING	Glenn R. Wamack		
HARRISON	Donald R. Stephens	Present	Present
MASON	Kelly Moss		
NICHOLAS	Geoffrey A. Peters		
PENDLETON	Rabert L. McKenney	Present	Present
ROBERTSON			
SCOTT	R. Kendall Brawn	Present	Present

TENTH DISTRICT

FAYETTE	Jomes W. Boker	Present	Present
	Jomes R. Beon	Present	Present
	Jahn V. Borders	Present	Present
	Jahn W. Collins	Present	Present
	Max A. Crocker	Present	Present
	W. Lisle Daltan	Present	Present
	Elvis S. Danaldsan, Jr	Present	Present
	Richard D. Flayd, IV	Present	Present
	Bill H. Harris	Present	Present
	Richord Hench		Present
	Rabert J. Hamm		Present
	Raleigh O. Jones	Present	Present
	Mogdolene B. Koran	Present	Present
	Dennis B. Kelly	Present	Present
	Doniel E. Kenody, Sr	Present	Present
	Williom D. Medino	Present	Present
	John M. Moore	Present	Present
	Andrew M. Moore, II	Present	Present
	Borboro A. Phillips		Present
	John W. Paundstone	Present	Present
	Andrew R. Pulito	Present	Present
	Borry N. Purdom		
	Nat Sandler		Present
	Glenn R. Sheorer	Present	Present
	Thamas K. Slobaugh	Present	Present
	Dovid B. Stevens	Present	
	John D. Stewort	Present	Present
	Jahn Rabert White	Present	Present
	Emery A. Wilson	Present	
	William O. Witt	Present	Present
JESSAMINE	Phyllis J. Carbitt		
WOODFORD	Narman S. Fisher	Present	Present

ELEVENTH DISTRICT

CLARK	Daniel Alon Ewen		
ESTILL	Jahn A. Pattersan		
JACKSON			
LEE	James B. Nable		
MADISON	William H. Mitchell	Present	Present
	Richard A. Stone	Present	Present
	Dovid S. Swon	Present	
MENIFEE			
MONTGOMERY			
OWSLEY			
POWELL	Chorles G. Noss		
WOLFE	Walloce L. Past, Jr		

TWELFTH DISTRICT

BOYLE	Arthur K. Rivord	Present	Present
	Scott B. Scutchfield	Present	Present
CASEY	Lewis E. Wesley	Present	Present
CLINTON	Caral B. Peddicard		
GARRARD	Paul J. Sides		Present
LINCOLN			
MCCREARY			
MERCER	George W. Noe	Present	Present
PULASKI	Danold E. Brown	Present	Present
	Donny M. Clork	Present	Present
	Joseph G. Weigel	Present	Present
ROCKCASTLE	Williom D. Dooley		Present
RUSSELL	H. Michoel Oghio	Present	Present
WAYNE	John W. Simmons	Present	Present

THIRTEENTH DISTRICT

BOYD	Kenneth R. Hauswald	Present	Present
	Howord B. McWhorter	Present	Present
	Mourice J. Ookley		Present
	Suson H. Prosher	Present	Present
CARTER			
ELLIOTT			
GREENUP	Monuel S. Gorcio		Present
	John O. Jones		
LAWRENCE	George P. Corter	Present	Present
LEWIS	Korl H. Smith	Present	Present
MORGAN	George R. Bellomy		
ROWAN	Morc L. Holbrook	Present	

FOURTEENTH DISTRICT

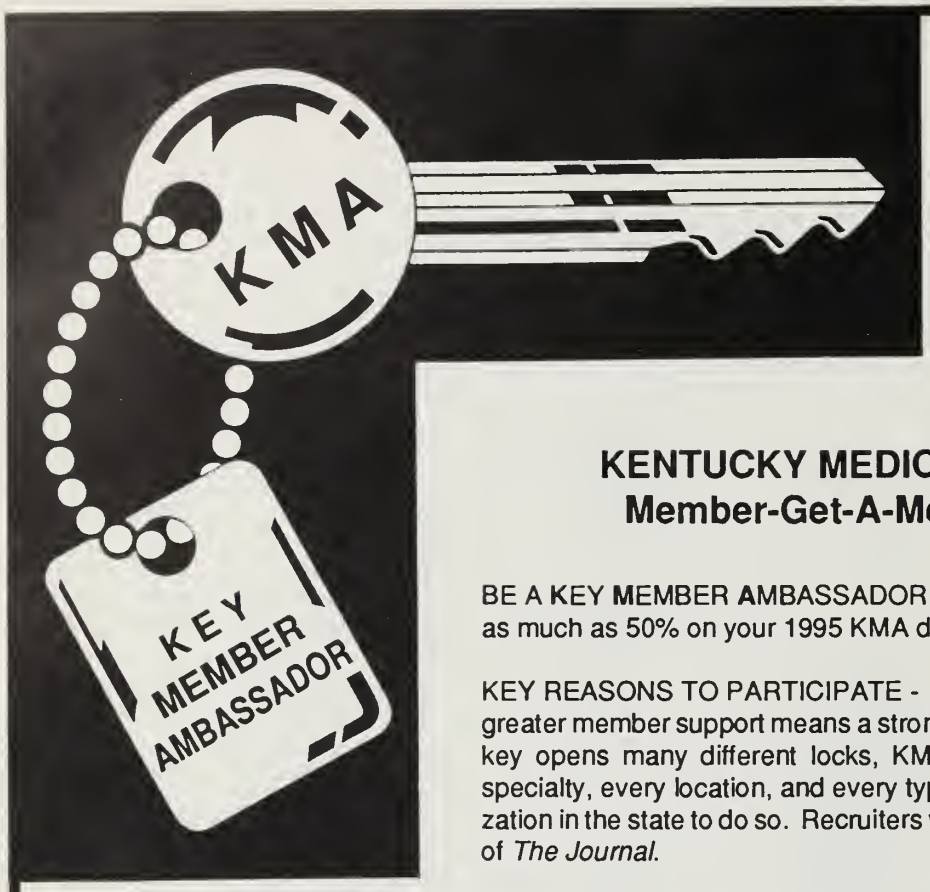
BREATHITT			
FLOYD	Nichalas R. Jurich		
	Raghu R. Sundaram		
JOHNSON	Franklen K. Belhasen		
KNOTT	W. Grady Stumba		
LETCHER	Van S. Breeding		
MAGOFFIN			
MARTIN			
PERRY	Mitchell Wicker, Jr		
PIKE	Dennis H. Halbert		
	Charles G. Nichals	Present	Present
	Elster D. Roberts	Present	Present

FIFTEENTH DISTRICT

BELL			
CLAY	Ira F. Wheeler		Present
HARLAN	F. Andrew Morfesis		Present
	Kenneth W. Smith		
KNOX	William S. Black		Present
LAUREL	David W. Douglos	Present	Present
LESLIE			
WHITLEY	Roymand J. Manaca, Jr		
	Jogdish S. Patil		

KMA Resident Physicians Sectian—Robin M. Floyd		Present
U of K Student Delegate—Mark Connon	Present	
U of L Student Delegote—Williom C. Thornbury, Jr		
KMA-HMSS—Williom D. Pratt	Present	

The infarmotion in the Roll Coll wos taken fram the attendance recard cords signed by the delegates prior to the meetings of the House, September 27 and September 29.



YOU are the KEY to the

KENTUCKY MEDICAL ASSOCIATION
Member-Get-A-Member Campaign

BE A KEY **M**EMBER **A**MBASSADOR - and unlock the opportunity to save as much as 50% on your 1995 KMA dues!

KEY REASONS TO PARTICIPATE - Besides the dues incentive to you. . . greater member support means a stronger, more unified, voice. As a master key opens many different locks, KMA represents physicians from every specialty, every location, and every type of practice - and is the only organization in the state to do so. Recruiters will also be recognized in future issues of *The Journal.*

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KEY TO RECRUITMENT - The most effective way to recruit new members is through a **personal** conversation or note conveying your own thoughts about why you are a member. Special recruiter kits containing brochures and information on benefits are available for your use.

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The campaign targets1994 membership. As a KMA Key Member Ambassador, the credit you earn for any new member joining before **April 1, 1994,** will be applied to your 1995 KMA dues. You hold the KEY to the amount of the discount:

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1-2	new members	- earn a	10%
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YES, I'm interested in the Member-Get-A-Member campaign. Send me a recruiter kit.

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I'd like a list of potential members:

- ❒ In my county
- ❒ In my specialty
- ❒ From my medical school class
- ❒ Faculty at my school
- ❒ Women
- ❒ International medical graduates

Mail to: *KMA Membership Dept., 301 N. Hurstbourne Pky, #200, Louisville, KY 40222-8512. Or call, (502) 426-6200.*

KMA's 143rd Annual Meeting



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(L to R) Reference Committee 1: John V. Borders, MD, Lexington, Chair; Susan M. Berberich, MD, Louisville; K. Thomas Reichard, MD, Louisville; Mohan K. Rao, MD, Madisonville; Charles G. Nichols, MD, Pikeville.



Reference Committee 2: William D. Pratt, MD, London; H. Michael Oghia, MD, Russell Springs; G. Irene Minor, MD, Berea, Chair; James F. Beattie, Jr, MD, Bowling Green; Thomas K. Slabaugh, MD, Lexington.



Reference Committee 3: Thomas M. Gadient, MD, Henderson; David A. D. Dao, MD, Elizabethtown; Beverly M. Gaines, MD, Louisville, Chair; Kenneth R. Hauswald, MD, Ashland; James R. Bean, MD, Lexington.



Reference Committee 4: Joseph G. Weigel, MD, Somerset; David W. Douglas, MD, London, Chair; Max A. Crocker, MD, Lexington; George R. Schrodt, Jr, MD, Louisville.



Reference Committee 5: William M. Renda, MD, Louisville, Chair; John M. Patterson, MD, Frankfort; Stephanie R. Hatfield, MD, Paducah; Jack C. Blackstone, Jr, MD, Ownesboro; Mark Cannon, Lexington.



Reference Committee 6: John D. Noonan, MD, Paducah, Chair; William C. Thornbury, Jr, Louisville; Robin M. Floyd, MD, Louisville; Susan H. Prasher, MD, Ashland; Vaughn W. Payne, MD, Louisville.

The William O. Roberts, MD Memorial Meeting of the Kentucky Medical Association

**Digest of Proceedings of the Regular Session of the*

House of Delegates

Danny M. Clark, MD, Somerset
Speaker of the House, Presiding

First Meeting
September 27, 1993

Danny M. Clark, MD, Speaker of the KMA House of Delegates, called the first Meeting of the 143rd Session of House of Delegates to order at 9:00 AM on Monday, September 27, 1993, at the Hyatt Regency Hotel, Louisville, Kentucky. He introduced the Vice Speaker, C. Kenneth Peters, MD, Jeffersontown, and KMA's Legal Counsel, Charles J. Cronan, IV, Louisville.

Following the invocation given by Harold L. Bushey, MD, Barbourville, the Chair of the Credentials Committee, Jack C. Blackstone, Jr, Owensboro, reported that a quorum was present. A motion was made, seconded, and carried to approve the Minutes of the 1992 Session of the House of Delegates as published in the December 1992 *Journal of the Kentucky Medical Association*.

William P. VonderHaar, MD, Louisville, Secretary-Treasurer, announced that the Scientific Session would begin at 8:50 AM on Tuesday, September 28, and the President's Luncheon would be held on Wednesday, September 29, at which time the new President would be installed. Dr VonderHaar reminded the Delegates that Reference Committees would convene at 1:00 PM on Monday. He then asked the House members to stand for a moment of silence in memory of KMA members who had died since the 1992 Annual Meeting.

William B. Monnig, MD, President, presented Educational Achievement Awards to H. David Wilson, MD, Lexington; W. David Hager, MD, Lexington; and Larry P. Griffin, MD, Louisville.

Speaker Clark announced that the Rules Committee had prepared a booklet outlining the rules the House should follow in its deliberations. Larry P. Wilson, MD, Louisville, Chair of the Rules Committee, summarized three recommendations the Rules Committee had proposed for changes at future Annual Meetings, and Dr Clark announced that the Delegates would vote on them at the Second Meeting.

Beryl Dodds, immediate past president of the KMA Alliance (formerly Auxiliary), presented AMA-ERF checks comprised of funds the Alliance had raised to benefit Kentucky's medical schools. Donald R. Kmetz, MD, Dean, accepted a check for $26,585.33 on behalf of the University of Louisville School of Medicine; and Emery A. Wilson, MD, Dean, accepted a check in the amount of $20,448.21 on behalf of the University of Kentucky College of Medicine.

Speaker Clark introduced the officers who presented their Reports. Each of the Reports was assigned to a Reference Committee as noted:

Report Number		Reference Committee
1	Report of the President William B. Monnig, MD, Edgewood	1
2	Report of the President, KMA Alliance Beryl Dodds, Madisonville	1
3	Report of the President-Elect Ardis D. Hoven, MD, Lexington	1
4	Report of the Speakers, House of Delegates Danny M. Clark, MD, Somerset C. Kenneth Peters, MD, Jeffersontown	1
5	Report of the Chairman, Board of Trustees Russell L. Travis, MD, Lexington	1
	Report of the Ad Hoc Committee on DNR James R. Bean, MD, Lexington	3
6	Report of the Secretary-Treasurer William P. VonderHaar, MD, Louisville	1
7	Report of the Editor A. Evan Overstreet, MD, Louisville	1
8	Report of the Delegates to AMA Donald C. Barton, MD, Corbin	1
9	Report of the Executive Vice President Robert G. Cox, Louisville	1
10	Kentucky Physicians Care Operating Committee Russell L. Travis, MD, Lexington	1
11	KMA Physicians Services, Inc. Russell L. Travis, MD, Lexington	1
12	Kentucky Medical Insurance Company Richard F. Hench, MD, Lexington	1
13	Scientific Program Committee Sonia R. Teller, MD, Louisville	2
14	Scientific Exhibits Committee Richard A. Kielar, MD, Lexington	2
15	Continuing Medical Education Committee W. David Hager, MD, Lexington	2
16	Council for Continuing Medical Education James L. Borders, MD, Lexington	2
17	Cancer Committee Clinton C. Cook, III, MD, Louisville	2
18	Physician Manpower Committee Robert R. Goodin, MD, Louisville	2
19	Hospital Medical Staff Section John D. O'Brien, MD, Louisville	2
20	Maternal Mortality Study Committee John W. Greene, Jr, MD, Lexington	3

****Editorial Note: A tape recording was made of the two meetings of the House of Delegates, and any member who wishes to examine the transcript of these Proceedings may visit the Headquarters Office and listen to the recordings.***

21	Committee on National Legislative Activities Donald C. Barton, MD, Corbin	3
22	Committee on State Legislative Activities Wally O. Montgomery, MD, Paducah	3
23	Committee on Professional Liability Insurance Wally O. Montgomery, MD, Paducah	3
24	Committee on Impaired Physicians Burns M. Brady, MD, Louisville	3
25	Committee on Care for the Elderly S. Philip Greiver, MD, Louisville	3
26	Committee on Medical Insurance and Prepayment Plans Donald R. Neel, MD, Owensboro	4
27	Committee on Claims and Utilization Review K. Thomas Reichard, MD, Louisville	4
28	PRO Advisory Committee James M. Bowles, MD, Madisonville	4
29	Committee to Investigate Changing Trends in Medicine Marjorie R. Fitzgerald, MD, Louisville	4
30	Committee on Maternal and Child Health J. Gregory Cooper, MD, Cynthiana	5
31	Technical Advisory Committee on Physician Services (Title XIX) A. O'tayo Lalude, MD, Louisville	5
32	Committee on Community and Rural Health Ardis D. Hoven, MD, Lexington	5
33	Committee on School Health, Physical Education, and Medical Aspects of Sports R. Quin Bailey, MD, Danville	5
34	Judicial Council William P. VonderHaar, MD, Louisville	6
35	Rural Kentucky Medical Scholarship Fund Donald R. Stephens, MD, Cynthiana	6
36	Physician-Attorney Liaison Committee Lynn L. Ogden, MD, Louisville	6
37	Membership Committee Harold D. Haller, Sr, MD, Louisville	6
38	Young Physicians Steering Committee Ford Threlkeld, MD, Frankfort	6
39	Medical Student Section Matt Shotwell, Lexington	6
40	Resident Physicians Section Baretta Casey, MD, Madisonville	6
41	Ephraim McDowell Cambus-Kenneth Foundation William B. Monnig, MD, Edgewood	6

New Business

New Business of the House was assigned to the Reference Committee indicated:

Resolution	Submitted by	Subject	Reference Committee
A	Board of Trustees	Freedom of Choice of Physician	1
B	Board of Trustees	Economic Entity	1
C	McCracken County Medical Society	Physician Assistants	3
D	Warren County Medical Society	House Bill 1	1
E	Board of Trustees	Medical School Training for Recognizing Domestic Violence	5
F	Young Physicians Steering Committee	Electronic Claims	5
G	Resident Physicians Section	Resident Medical Staffs in Kentucky Training Hospitals	2
H	Boyle County Medical Society	Publicity Campaign	6
I	Jefferson County Medical Society	Nursing Home Regulations	3
J	Jefferson County Medical Society	Assistants at Surgery	4
K	Jefferson County Medical Society	Insurance Industry Liaison	4
L	Madison County Medical Society	Proposed Nerve Gas Incinerator	3
M	Legislative Committee of the Warren County Medical Society	Cost Containment Subcommittee of the Health Care Reform Task Force	1
N	Pulaski County Medical Society	Nursing Home Beds	3
O	Warren County Medical Society	Use of "*EXCESS*" Medicaid Funds to Balance the General Budget	1

Vice Speaker Peters announced the meeting locations for the Nominating Committee and for Trustee Districts electing Trustees and Alternate Trustees. He reminded the Delegates that the Nominating Committee would report at the close of the first Scientific Session on Tuesday morning.

The names of the Nominating Committee members were announced: Joseph G. Weigel, MD, Somerset, Chair; John V. Borders, MD, Lexington; William C. Harrison, MD, Owensboro; John M. Karibo, MD, Louisville; and Frank K. Sewell, Jr, MD, Henderson.

An update on health care reform was presented, followed by a question and answer session. The Speaker adjourned the First Meeting at 11:15 AM.

Second Meeting
September 29, 1993

Speaker Clark called the Second Meeting of the 1993 Session of the KMA House of Delegates to order at 7:00 PM on Wednesday, September 29, 1993. G. Irene Minor, MD, Berea, gave the invocation, and Jack R. Blackstone, Jr, MD, Owensboro, Chair of the Credentials Committee, reported that a quorum was present.

Secretary-Treasurer VonderHaar recognized guests from neighboring state medical associations who had attended the Annual Meeting. Included were Arthur R. Traugott, MD, President, Illinois State Medical Society; George E. Broman, MD, President, Medical Society of Virginia; Walter A. Reiling, MD, President, Ohio State Medical Association; and C. Dyke Egnatz, MD, Immediate Past President, Indiana State Medical Association.

Russell L. Travis, MD, Chair, Board of Trustees, made a motion on behalf of the Board that Paul J. Parks, MD, Bowling Green, be reelected to a four-year term on the Judicial Council. The motion was seconded from the floor and carried.

President Monnig introduced Randolph D. Smoak, Jr, MD, a member of the AMA Board of Trustees, from Orangeburg, South Carolina. Dr Smoak noted that unity of the profession is of paramount importance. He provided an overview of President Clinton's health care reform plan, and it was noted that a summary of the plan, along with AMA's reaction, had been distributed to each House member.

Richard F. Hench, MD, Lexington, Chair of the Kentucky Medical Insurance Company Board of Directors, presented an update on Kentucky Medical's activities.

The Speaker then called for the Reference Committee Chairs to present their Reports.

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF REFERENCE COMMITTEE NO. 1

John V. Borders, MD, Lexington, Chair

1. Report of the President
2. Report of the President, Alliance
3. Report of the President-Elect
4. Report of the Speakers, House of Delegates
5. Report of the Chair, Board of Trustees, *except* for the following:
 Report of the Ad Hoc Committee to Implement Resolution M (1991)
 (Referred to Reference Committee No. 3)
6. Report of the Secretary-Treasurer
7. Report of the Editor
8. Report of the Delegates to AMA

9. Report of the Executive Vice President
10. Report of Kentucky Physicians Care Operating Committee
11. Report of KMA Physicians Services, Inc
12. Report of the Kentucky Medical Insurance Company
 Resolution A — Freedom of Choice of Physician
 (Board of Trustees)
 Resolution B — Economic Entity
 (Board of Trustees)
 Resolution D — House Bill 1
 (Warren County Medical Society)
 Resolution M — Cost Containment Subcommittee of the Health Care Reform Task Force
 (Legislative Committee of the Warren County Medical Society)
 Resolution O — Use of "*EXCESS*" Medicaid Funds to Balance the General Budget
 (Warren County Medical Society)

ITEMS FOR CONSENT

Reference Committee No. 1 reviewed the following items and recommends they be filed, by consent of the House, without discussion:

2. Report of the President, Alliance — filed
3. Report of the President-Elect — filed
4. Report of the Speakers, House of Delegates — filed
5. Report of the Chair, Board of Trustees, *except* for the following: Report of the Ad Hoc Committee to Implement Resolution M (1991) — filed
6. Report of the Secretary-Treasurer — filed
7. Report of the Editor — filed
8. Report of the Delegates to AMA — filed
9. Report of the Executive Vice President — filed
11. Report of KMA Physicians Services, Inc. — filed
12. Report of the Kentucky Medical Insurance Company — filed

Mr Speaker, Reference Committee No. 1 recommends adoption of the Consent Calendar as a whole.

Report of the President, Alliance

This has been an interesting and exciting year for the Kentucky Medical Association Alliance. Across the Commonwealth our members have raised money for AMA-ERF and health scholarships. We organized and held health and safety fairs and environmental health fairs. We had programs and projects on bicycle safety and AIDS education. We worked tirelessly for a seat belt law and for health care reform.

Members of the Alliance continue to serve as active members of the KMA Legislative Committee and on the KEMPAC Board. Our Executive Committee members and county presidents have been added to the mailing list for legislative updates so that information is available in a timely manner. Health care reform information was presented at Fall Board by Don Chasteen and by Dr William B. Monnig. Information was also available at Winter Board and at our Annual Convention in April when we were pleased to have Dr Monnig speak to us again. Members of the Alliance were invited to participate in a KMA briefing in Lexington during the Special Legislative Session on Health Care Reform and we were very well represented.

Family violence is the single largest cause of injury to women in the United States. As many as 35% of women who visit hospital emergency rooms are there for symptoms related to ongoing abuse, but perhaps as few as 5% of them are identified as victims of family violence. The prevalence of family violence and its consequences on society make it an issue that every American should address. Those of us in the medical community should be particularly concerned, since family violence is a pressing health issue. Accordingly, the KMA Alliance held two family violence seminars. The purpose of these seminars was to provide information about the extent of the problem of family violence; an overview of community resources; and suggestions about how we, both individually and collectively, can work to break the cycle of violence. We were pleased to welcome members from Illinois, Indiana, and Ohio to our seminars. In addition, members of the KMA Alliance were encouraged to join the National Coalition of Physicians Against Violence. The purpose of this Coalition is to work with other concerned groups and individuals to develop local family violence prevention committees that can set agendas to combat the problem. The Coalition will also serve as a source of information for physicians, providing them with newly updated guidelines on child physical and sexual abuse, domestic violence, and elder abuse.

The opportunity to network with other auxiliaries and alliances from across the country is a big benefit of our national membership. The KMA Alliance took seven county presidents-elect to Leadership Confluence in Chicago this year to take advantage of the special training provided by our national officers and committee representatives. County presidents-elect from Daviess, Fayette, Henderson, Hopkins, Jefferson, McCracken, and Northern Kentucky were able to take advantage of this unique experience. The informational seminars and leadership training sessions offered by our national organization are truly exceptional.

Many factors contribute to the high standard of medical care in the United States. Among them is the expertise of the physicians providing that care. The American Medical Association Education and Research Foundation (AMA-ERF) is a non-profit, public foundation dedicated to ensuring that medical schools and students receive funds to supplement the cost of high quality education and training. Kentucky excels in its efforts in support of AMA-ERF on both the county and state level, frequently receiving national awards. From May 16, 1992, through May 15, 1993, the KMA Alliance raised $54,286.14, an increase of $134.81. Combined with physicians' contributions of $1,560, the grand total for 1992-93 was $55,846.14. This year Kentucky placed fourth among all states in per capita AMA-ERF contributions and Boyd County placed first among all counties across the country in per capita contributions.

In addition to raising money for AMA-ERF, county auxiliaries and alliances in Kentucky raised money for health scholarships. During 1992-93, the KMA Alliance and its constituent auxiliaries and alliances awarded more than $38,700 in health scholarships. This money was raised in a variety of ways, including Christmas auctions, a country and western dance, an attic sale, and a day at the track. One auxiliary, McCracken County, now an alliance, raised over $21,000 for next year's scholarships with their Christmas Gala.

Physicians' spouses across the Commonwealth are working to improve the health of Kentuckians by being directly involved with health projects within their communities, and by helping to provide trained health care professionals for the future.

Beryl Dodds
KMAA President 1992-93

Report of the President-Elect

It is an honor and privilege to report to you as President-Elect. Although I have had the good fortune of being involved in KMA activities before this year, this period has been particularly rewarding. This time of learning, observing, and working has brought me a new appreciation of the commitment by KMA to the protection and advocacy of the profession.

In my view, this has been one of the most critical years that organized medicine and physicians have yet faced. During this year, a number of issues were crucial, and KMA played a central role for medicine, both at the state and national levels. KMA was instrumental in developing guidelines for the reporting and practices of HIV infected physicians. This effort was undertaken to fulfill federal requirements, but the guidelines developed with the Licensure Board and the state Health Department are Kentucky-specific and are fair for physicians.

KMA also played a pivotal role in addressing family violence and related issues. Through a KMA Subcommittee on Domestic Violence and the efforts of other KMA committees, we have worked with the state Attorney General's office and other agencies to help bring more attention and, hopefully, more relief to this issue which plagues society and our patients.

Obviously, the bulk of our efforts has been in the area of health care reform, and a study of the progress of this issue through social and legislative avenues has been a science unto itself. At the state level, many KMA representatives were intimately involved in the Task Force meetings and testimony initiated by the Governor prior to development of his reform bill. Through the Task Force process, up to and through the special session, officers, staff, and many other diligent members spent countless hours resolv-

ing our own concerns internally and communicating a representative view to all legislative levels.

At the national level, KMA was involved in two separate trips to Washington to carry your voice to our congressional delegation on health care reform and, particularly, budget reconciliation issues that affected Medicare reimbursement. The success of our efforts, together with all members of the federation nationwide, resulted in a reconciliation package that you are undoubtedly familiar with by now. That success was equivocal but just one encounter in an ongoing process.

The final focal issue for KMA this year was the suit against the state regarding the tax on physicians' gross incomes. The initiation of this suit was a difficult issue and not quickly made by the Board of Trustees. When the Board met to initiate the suit, the decision did not come easily. All viewpoints were expressed and after thoughtful consideration, a consensus was reached which, I believe, fairly represents the majority of physicians' opinions in the state. Finally, KMA's opinion was, I feel, founded on the perception that the tax was a matter of political expediency and, therefore, transitory. While we should be particular about the freedoms we choose to contest in a legal arena, this decision, though not easy, seems sensible.

Next year will likely be even more critical. Based on my experiences to date, the question of substantive federal enactment of health system reform is equivocal. The enactment, however, of future state-level directives is likely. If nothing else, KMA's suit against the Commonwealth may prompt either mitigating or more onerous legislation.

In the coming year, I do not see things becoming clearer or easier, but I do commit careful, objective, and considerate effort on your behalf. I humbly thank you for the honor you have given me in choosing to allow me to serve.

Ardis D. Hoven, MD
President-Elect

Report of the Speakers, House of Delegates

Your Speakers would like to welcome you to the 143rd KMA Annual Meeting, which is dedicated to the memory of William O. Roberts, MD, who was President of KMA in 1913. Your officers and staff have spent considerable time and effort in attempting to make the entire meeting valuable to you and we particularly urge your attendance and attention at both meetings of the House.

The first meeting of the House will convene at 9:00 AM on Monday, September 27. At 10:00 AM a special portion of Monday morning's activities will be devoted to health care reform issues. It is hoped that we can bring you up to date on the status of the pending suit between the KMA and the Commonwealth, relating to the gross revenue tax and to provide up-to-the-minute information on pending state legislative initiatives. Reference Committees will begin at 1:00 PM, and we earnestly solicit your attendance and input in these important policy sessions.

The Rules Committee of the House has met this year and is posing three rules you are asked to vote on relating to the composition and operation of Reference Committees. We hope that you will feel free to seek out the Speakers, the Chairman, or members of the Rules Committee if you feel other changes are in order.

We look forward to an informative meeting that will result in policy to direct the Association during the coming year, which will have many critical measures to be confronted. We are, of course, available at any time to any member for advice, counsel, or suggestions.

Danny M. Clark, MD
Speaker, House of Delegates

C. Kenneth Peters, MD
Vice Speaker, House of Delegates

Report of the Chair, Board of Trustees

This has been like no previous year in KMA history. I expect the new Associational year will be more of the same . . . and maybe worse. I do not know how to appropriately convey to you my praise for your officers who have given an unprecedented amount of time to work on behalf of the physicians of our state.

President Monnig scheduled patients only two days a week much of the time to enable him to devote more time to health system reform and its many meetings and considerable travel. He, President-Elect Hoven, and Secretary-Treasurer VonderHaar, along with your Chair, testified jointly and separately on many occasions. Our Legislative Quick Action Committee Chair, Wally O. Montgomery, MD, called our group together weekly because things moved at a fast pace. Past President Scheen was there to offer counsel, and other physicians were called in to help . . . and they willingly did so. Extra meetings of the Executive Committee and Board of Trustees were necessary. Many things were happening and changing fast — too fast for us to keep the membership totally tuned in, so I plead with you that some faith in your elected officials was essential, and a little support appreciated. Misinformation and rumors run rampant in such times, and we have tried to cope with them the best we could. Solutions don't come with a *Wheel of Fortune* spin of the dial, but through deep thought, hard work, and the art of negotiations.

KMA is about a lot of things, significant things that impact our professional lives daily and, thus, commitments to them went on as usual. The more than 40 committees continued all their specialized work and their annual reports summarize their activities. Please read them.

We also continue our quest for a new headquarters office. You will recall our headquarters building, built in 1960-61, was outgrown and sold in 1991. We are now leasing with the intent to be in a new headquarters building, housing us and KMIC, no later than late 1996 or early 1997. We are now in the final phase of purchasing land for the building which is located near our current office, and is part of a park-like setting. We feel it will offer us many advantages.

We must also continue our quest for unity. The attacks on medicine today are more frequent and more severe than at any time in our past. Yet, as a profession, we seem to see more turf battles and internal haggling than the strong unification we need. We must fight for the profession as a whole and leave a heritage of which we will be proud. I beg you to stay involved in organized medicine to learn for yourself what is really happening, and to support your peers who fight the battles for us. During the past year, we recognize that we received help from many of you when called upon. We thank you and urge your continuance.

As a young boy, I'd often go to the Saturday afternoon matinee. A staple of the movies in those days was the serial. Throughout childhood and adolescence the serials were always there. Something happened every week; the story never ended . . . and you were always left hanging. Efforts to reform the health care system remind me of those serials. Something happens every week; the end is never in sight . . . and we're always left hanging.

I reported last year that 1992 was the busiest year ever for KMA. It turns out we were just getting warmed up. Since our last report, the focus of your officers and staff has been almost totally on the efforts of the state to revise Kentucky's health system.

The Governor's Task Force on Access and Affordability completed its work in the fall of 1992, and a final report was developed which summarized the recommendations of the Task Force. A broad cross section of highly motivated, knowledgeable people served on the Task Force. They gave freely of their time, attending not only Task Force meetings, but the numerous "Town Forums" held across the state.

Originally, the Task Force report was to be sent to the Governor's Commission on Health Care Reform which would in turn develop the Task Force recommendations into a legislative format. The Commission's legislation would then be taken back to town forums for public response, and a special session of the General Assembly would be called in November 1992.

As the Commission began its work, it became apparent that the Governor, and particularly his staff, never intended to base health care reform on the Task Force's work, opting instead to adopt and introduce a plan developed solely by the administration. Secondly, opposition to the Governor's plan from legislative leadership went from subtle complaints to disdain for the entire package. As Governor Jones' plan began to take shape, KMA took every opportunity directly or indirectly to suggest appropriate changes.

The key component to the administration's proposal was a tax on employers who do not provide health insurance for their employees. Reve-

nue from that tax would be used to fund basic health benefit plans for the uninsured through large groups including state employees, Medicaid recipients, teachers, prisoners, and others who chose to opt in. There was little legislative or public support for the employer mandate and other troubling aspects of the plan, including choice of provider, and the Special Session was delayed until May 1993.

While the Governor's plan was unfolding, KMA participated in a parallel process with a goal of developing a reform plan meeting the Governor's contradictory but laudable objectives of universal access and cost containment, but from a nonregulatory approach. Recognizing that the private sector was in the best position to develop such a plan, a coalition composed of the Kentucky Medical Association, the Kentucky Hospital Association, the Kentucky Chamber of Commerce, Kentucky Blue Cross and Blue Shield, and Humana/Galen labored many hours over a period of seven months developing the Infrastructure Model for Health Care Reform. This model emphasized a competitive approach based on phased-in access and cost containment strategies. Targets for reducing the rate of increase in health costs would be established coincidental with reforms to address cost provocative factors such as professional liability and health insurance practices. If cost containment goals weren't met in a given time frame, more regulation would be imposed on the system. If the effects on cost were still ineffective, a totally regulated system would be imposed. This concept was based on the fact that overall reform at the federal level would probably be imposed in a similar time frame.

The development of this plan was time-consuming and arduous. Many diverse views and strongly held philosophies were represented, but amazingly we were able to reach a general consensus. The proposal was introduced in the Special Session, but by that time it became clear that there was no support for total health care reform, and the General Assembly would simply address Medicaid funding and adjourn.

During the course of events leading up to the Special Session, KMA officers and staff continued to communicate with the membership through newsletters and special correspondence. We appeared at county medical society meetings, hospital medical staff meetings, and Trustee District gatherings; spoke to specialty societies; participated in regional and local Chamber of Commerce meetings; and appeared on radio and television programs to discuss health system reform. In all, KMA leaders and staff participated in over 300 meetings on health system reform. We attended and participated in several national meetings on reform and learned that virtually every state was trying to deal with this complex issue.

At the outset, KMA was able to meet with administrative officials and influence some aspects of the proposal. Early versions proposed to disband the Kentucky Board of Medical Licensure and replace it with a "superboard" composed of a majority of nonprofessionals, with only token physical representation. Due to KMA's objections, this unacceptable provision was withdrawn from the plan sent to the General Assembly. Other unacceptable provisions included citizen-dominated panels to develop practice parameters and a recommendation for a 6% provider tax to fund Medicaid and services to indigent persons.

The original proposal called for a three-person health care authority with no providers. Again, due to KMA efforts, the proposed authority was expanded to five members with two providers in the bill introduced by the administration. However, other proposals were introduced in the Special Session which would exclude providers from the authority. We need to remain vigilant for there is a distinct possibility that such a structure could prevail in any future action the General Assembly ultimately takes on this issue.

Throughout the year, considerable focus was given to the plan to impose a tax on providers to help fund the Medicaid program. As onerous as the tax is, it pales in comparison to the more objectionable reform measures considered by the General Assembly in May and which undoubtedly will be reconsidered in any future regular or special sessions.

While KMA strongly opposed the provider tax and is challenging its constitutionality, the passage of the tax demonstrates that General Assembly members who live and work in our local communities can and will enact legislation unacceptable to physicians. If the tax serves as a wake up call to Kentucky physicians, hopefully we will see greater physician political activity where it does the most good — by local physicians at the local level.

As this report is written, the Special Legislative Task Force on Health System Reform has begun its work. It has a purpose and in all probability will generate a bill that can be enacted into law. This spring, the General Assembly tried to deal with the Governor's reform proposal which essentially was dead upon arrival. Its members didn't understand the issues and were inundated with ideas, suggestions, and proposals. Embarrassed over the cost of the Special Session and the lack of results, leadership abruptly adjourned the Session. However, "the ball is now in the General Assembly's court." The Governor very tactfully got them to agree to be a player in this reform effort, and the final product will be theirs to defend.

The leadership of the General Assembly now has to prove it can accomplish something and must develop a plan politically acceptable to the membership before it's called into session. Whether or not it's acceptable to KMA is another matter. The tone of the Task Force is "don't tell us your history or your problems . . . just give us answers or don't waste our time."

To address these specifics, the Board, in a special called meeting in June, voted to support employer-based universal coverage through the imposition of a 3.75% payroll tax on employers who do not provide health insurance; implementation of a broad-based tax to fund Medicaid and other indigent care programs, in lieu of provider taxes; and extending the 6% sales tax to all services. Such a tax would encompass all individuals and entities furnishing a service and would be a pass-through tax to consumers. The Board believes this is a fair approach to the funding issue and a reasonable way to begin to achieve coverage for all Kentuckians, regardless of ability to pay.

Physicians' views on health system reform vary as widely as the private sector's. KMA has made every effort to build a coalition of thought and consensus within the profession on ways we can reform the system, maintain quality and freedom of choice for our patients, yet still remain in the mainstream of medical thought. For those of us who have had to make on-the-spot decisions that would affect a lot of people, this has been a trying experience. The pressure will only increase in the coming months.

It has been a unique experience to serve as your Chair. I have learned much, and have appreciated the opportunity to do so. I have tried to serve you to the best of my abilities.

A report on the Legal Trust Fund is included annually in the Chair's Report. Expenditures were made during the past year of $30,751.01 due to the provider tax lawsuit, and the Fund's balance as we prepared this report was $216,279.85.

The following summary of Board meetings is designed to give you a quick review of your Board's activities. Routine Board meetings last two days, and complete Minutes of all Board Meetings will be provided to Reference Committee No. 1. I also remind you that the committee reports give you additional insight into your Association's involvement on your behalf.

KMA is working hard for you and every physician every day. Participate and get behind it. KMA is our ticket to the future of our profession.

SUMMARY OF BOARD MEETINGS

First Meeting, September 17, 1992

Acting as temporary Chair, KMA Secretary-Treasurer William P. VonderHaar, MD, introduced the newly elected members of the Board and the new officers: Ardis D. Hoven, MD, Lexington, President-Elect; David C. Liebschutz, MD, Danville, Vice President; Harry W. Carloss, MD, Paducah, Trustee, 1st District; William H. Klompus, MD, Madisonville, Trustee, 3rd District; Salem M. George, MD, Lebanon, Trustee, 4th District; Scott B. Scutchfield, MD, Danville, Trustee, 12th District; and E. D. Roberts, MD, Pikeville, Trustee, 14th District.

The Board elected the Executive Committee members to serve with the President, President-Elect, Vice President, and Secretary-Treasurer for the 1992-93 KMA year. Russell L. Travis, MD, Lexington, was reelected Chair of the Board, and John W. McClellan, MD, Henderson, was elected Vice Chair. William H. Mitchell, MD, Richmond, and Don R. Stephens, MD, Cynthiana, were named as Trustees-at-Large.

It was noted that the KMA Executive Committee members also serve as the Boards of Directors of KMA Physicians Services, Inc (KMA's holding company), and the KMA Building Corporation.

The Board also made changes to the Kentucky Foundation for Medical Care Board of Directors in accordance with KFMC's Bylaws, and appointed KMA committees for the following year.

Second Meeting, December 17, 1992
Convening in a regular session, the KMA Board of Trustees met on December 17, 1992, at the Holiday Inn Hurstbourne in Louisville. The Board members heard reports of the President, the Secretary-Treasurer, the Senior Delegate to AMA, the Vice Dean of the University of Louisville School of Medicine, the Commissioner for Health Services, Chair of the KEMPAC Board of Directors, and Chair of the KMIC Board of Directors. It was noted that the Boards of the KMA and the Kentucky Medical Insurance Company had met in joint session the previous day to discuss matters of mutual interest.

The Director of the Medicare Part B Program, James B. Holloway, Jr, MD, also updated the Board members regarding activities in the Medicare Program. Representatives of Kentucky Blue Cross and Blue Shield made a presentation regarding the KMA-endorsed BCBS plan for the membership.

Detailed reports were given concerning the activities of the Committees on National and State Legislative Activities, which included plans for the Special Session of the Kentucky General Assembly in 1993. The Board members held a lengthy discussion about health care reform, to be considered by the Special Session, and took note of policy which had been adopted by the 1992 House of Delegates in this regard.

The Board directed that, pending permission of the Kentucky Supreme Court, an amicus curiae brief be filed in a "wrongful life" suit. Appointments were made to the KMIC Board Election Nominating Committee, and the report of the Membership Committee was accepted, which noted KMA has experienced the highest percentage and number increase in membership in more than 22 years. The Board members approved a policy on HIV/HBV-infected physicians, adopted a modified CME Mission Statement, and approved names for submission to the Cabinet for Human Resources for service on a Drug Utilization Review Committee.

The Board members also approved updating a brochure on child abuse that had been developed several years ago, and endorsed action taken to purchase a building lot in the Hurstbourne Green development in Louisville for a future headquarters for KMA and the Kentucky Medical Insurance Company. A report on cost-cutting measures to be implemented in the *Journal of the Kentucky Medical Association* was accepted, and action taken to implement directives of the 1991 House of Delegates was also endorsed.

Third Meeting, April 14-15, 1993
The KMA Board of Trustees held its two-day spring meeting on April 14-15, 1993, at the Hyatt Regency Hotel in Louisville. The Board members heard reports from the President, the Secretary-Treasurer, the Auxiliary President, the Senior Delegate to AMA, the Vice Dean of the University of Louisville School of Medicine, the Chair of the KMIC Board of Directors, the President of the Board of Medical Licensure, and the Commissioner of the Bureau for Health Services.

The Board approved the expenditure of $2,600 for the Subcommittee on Domestic Violence to develop packets of information on domestic abuse, and adopted a budget for the 1993-94 Association year. Nominees were selected for the KMIC Board of Directors, as well as for service on Governor-appointed councils. The Board members approved draft regulations submitted by the Board of Medical Licensure which would require mandatory continuing medical education as a condition of licensure. Legal cases of interest to KMA were discussed, and the reports of the Membership Committee and the Ad Hoc Committee on the KMA/KMIC Headquarters Location were accepted.

Comprehensive reports were given concerning the activities of the Committees on National and State Legislative Activities. The Board spent considerable time discussing Governor Brereton Jones's plan for health care reform and the anticipated Special Session of the Kentucky General Assembly. The Board members also finalized recommendations for current KMA policy and strategy in regard to health care reform.

Fourth Meeting, June 17, 1993
A special meeting of the Board of Trustees was held on June 17, 1993, at the request of the Quick Action Committee. The Quick Action Committee had met earlier in the month to consider the results of the Special Session of the Kentucky General Assembly, called to address health care reform; and specifically, HB 1, the provider tax bill. A consensus was sought from the Board in formulating positions on specific aspects of the Governor's proposal for reform.

Legal Counsel advised the Board members regarding a possible legal challenge to HB 1, which would tax only health care providers to generate revenue for indigent health care. After a thorough discussion, the Board voted to file a lawsuit challenging the constitutionality of the provider tax bill (HB 1), and to seek an injunction in the case.

The Board also voted to reaffirm support for universal access and to support an employer mandate of 3.75%, a sales tax on professional services, and a tax on alcohol and tobacco, if needed.

Fifth Meeting, August 11-12, 1993
The KMA Board of Trustees held its fifth meeting of the Association year on August 11-12, 1993, at the Oxmoor Steeplechase Clubhouse in Louisville. Reports were given by the President; Secretary-Treasurer; President, KMA Alliance; Senior Delegate to AMA; and Chair, Committee on State Legislative Activities. In addition, the Board heard presentations from the Board Chair of the Kentucky Medical Insurance Company; President of the Board of Medical Licensure; Dean, University of Kentucky College of Medicine; and the Deputy Commissioner for Health Services.

An update was given on the status of health care reform in Kentucky; and the Board reiterated its support of the use of the Legal Trust Fund to challenge the constitutionality of HB 1, a provider tax bill, recently passed by the Kentucky General Assembly in special session to fund health care reform.

The Board members approved a stock purchase program for Board members and staff of Kentucky Medical; heard details of the merger of Kentucky Blue Cross and Blue Shield with its counterpart in Indiana; and reappointed all current *Journal* Editors.

In other action, the Board authorized a $10 voluntary assessment for the Legal Trust Fund to be included with the 1994 dues billing; authorized the addition of the Spencer County Medical Society to the Tri-County Medical Society; and reappointed the KEMPAC Board of Directors.

The Board reviewed its Ad Hoc Committee reports, as well as each final committee report to be submitted to the 1993 House of Delegates. Several Resolutions were authorized for submission to the House. A listing of actions taken to implement the directives of the 1992 House of Delegates was distributed, and it was noted that the same information would be sent to every Delegate as an addendum to the 1993 Chair's Report. It was agreed to invite Alternate Trustees to attend the next meeting of the Board to be held during the Annual Meeting on Sunday, September 26.

Executive Committee
The KMA Executive Committee meets between sessions of the full Board to guide the day-to-day operations of the Association and to give extensive consideration to major subjects presented to the Board of Trustees. The Executive Committee is composed of eight officers and trustees and during this past year, met on seven occasions with health system reform dominating the agenda. On your behalf, these physicians work many hours and travel many miles.

Quick Action Committee
Four of the Executive Committee members above serve as the Quick Action Committee: the President, President-Elect, Chair of the Board, and Secretary-Treasurer. In addition, during legislative sessions, the Chairman of our State Legislative Activities Committee also serves as Chairman of this group. The Quick Action Committee held a record number of meetings this year, in that we met weekly during the legislative session and nearly weekly throughout the year on health system reform and with allied groups. I estimate we had 25 to 30 meetings since last September. There can be no group who gives more and asks for less. They are totally dedicated, always available, and I could ask for no better group to represent our profession. I hope every KMA member shares that gratitude.

Ad Hoc Committees
This year we had three ad hoc committees doing a great deal of work. The Ad Hoc Committee on KMA/KMIC Headquarters Location, chaired by President Monnig, had a number of meetings and finalized plans for our purchase of a site to locate our new headquarters office. We appreciate their effectiveness and successful conclusion.

The Ad Hoc KMA/KMIC Liaison Committee, Chaired by President-Elect Hoven, has done much to ensure our two organizations' boards and staff are fully aware of each others' goals, and utilize a cooperative spirit in helping fulfill the mission of each. The Committee planned and imple-

mented a joint meeting between the Boards of KMIC and KMA last December. That session resulted in another being planned for December 1993.

The Ad Hoc Committee to Implement Resolution M (1991) continues to meet to develop a uniform, coordinated, and rational approach with respect to the terminally ill patient who does not wish to be resuscitated or to receive extraordinary life prolonging treatment in the pre-hospital environment. Development of DNR forms, identification of patients, and other related matters are a part of their charge. Much progress has been made, and we are indebted to James Bean, MD, of Lexington, and his committee.

In closing, I reiterate it has been an unparalleled year in our history. With all of the external pressures put upon us, however, we were able to achieve many accomplishments because of our internal forces. I urge the membership's renewed support as I thank each of you, the committees, the Board of Trustees, and the House of Delegates for your efforts this past year.

It is only with the help of an experienced and dedicated staff that we can even attempt to fulfill the needs of this Association. My heartfelt thanks goes to each and every staff member, for so few of us know of their workload and untiring efforts on behalf of Kentucky physicians. They carry their load. If all of us do our part as members and maintain our proper role as patient advocates, we will succeed.

Russell L. Travis, MD
Chair

Report of the Secretary-Treasurer

It is my privilege to report to you as Secretary-Treasurer and to announce the strong and viable status of the Association.

Most important to note is that KMA membership reached an all-time high this year, with more than 4,000 active members. The largest membership increase was accomplished this year, with a net gain of 203 members and the largest percentage increase of 5.4%. Reflected in these totals is very good participation by the students and residents at both universities. We should be gratified with this high, but should note that many areas of our state have a relatively low membership rate. The Association's thanks go to the Membership Committee for its notable efforts in this and previous years.

It is important, also, to recognize that as the demographics of the profession change, areas of change should be focused for KMA's attention. The number of women physicians continues to grow, as does the relative proportion of young physicians. Their efforts and energies are sorely needed, and they are encouraged to be available to the Association.

This year the Board welcomed new Trustees Harry W. Carloss, MD, Paducah; William H. Klompus, MD, Madisonville; Salem M. George, MD, Lebanon; Scott B. Scutchfield, MD, Danville; and E. D. Roberts, MD, Pikeville.

From a financial perspective, your Association continues its strong fiscal status, and your attention is directed to the Auditor's Report for detailed information. This year the Board voted to continue the $10 Legal Trust Fund assessment to support KMA's efforts in its suit against the Commonwealth relating to the gross tax on physician revenues and other legal undertakings.

Work was continued this year on plans for a new location for the Headquarters Office. Long-range plans made at the time of the sale of the old KMA building included eventual new construction. In conjunction with KMIC, land was located and site purchase plans were finalized. Tentative plans called for construction to begin in 1995.

In spite of what seems to be a universal clamor for health system reform and significant change to the Medicaid Program, the Kentucky Physicians Care program continued this year at a steadfast pace. Your attention is directed to the KPC Operating Committee report for more details, but it is gratifying to know that physicians' commitment to providing needed care, regardless of paying source, has continued unabated.

If anything, the business of the Association continues to grow with increased onslaughts on the profession and the Association's activities. As Secretary-Treasurer, I have had the benefit of observing the efforts of many physicians, from the local doctor to members of the Board of Trustees, who assiduously carry on the time-honored tradition of the concerned citizen-physician. I know that tradition will continue, and I am honored to be a part of it. Thank you for affording me the opportunity to serve.

William P. VonderHaar, MD
Secretary-Treasurer

Report of the Editor

The *Journal of the Kentucky Medical Association* is now in its 90th year and continues to receive and appreciate the support of the membership. Loyalty to the publication permits the editors to provide members with relevant continuing medical education and information; to promote the ideals of the Kentucky Medical Association; to encourage scholarship and good will among Kentucky physicians; to provide a two-way forum for medical opinions; and to disseminate information specifically applicable to the health care of Kentuckians — all in the highest quality possible within its financial framework.

A state medical journal is a historical gold mine. Events occurring in medicine within the state are documented nowhere else, and this information becomes increasingly valuable as the years go by. The *Journal* represents a principal membership benefit. It is a valuable publication and helps to both recruit new members and retain current ones.

During 1992 the *Journal* featured 24 original scientific articles representing the efforts of 73 authors; 5 Grand Rounds contributions from the University of Louisville and University of Kentucky medical schools representing 11 authors; and 4 special articles representing 8 authors. Also featured during the year was a special series entitled "Kentucky's Bicentennial — A Brief Overview of 200 Years of Medical Practice and the Physician," written by KMA Historian Eugene H. Conner, MD. In addition articles by and about women in medicine; several socioeconomic articles; a preliminary program for the 1992 Annual Meeting, as well as the entire proceedings of that meeting; several insightful contributions by Book Review Author Stephen Z. Smith, MD; Auxiliary updates; and numerous editorials and letters discussing medical issues of interest to our membership were published.

The *Journal* also published the "1992 KMA Legislative Handbook," a comprehensive collection of legislative information designed to equip KMA members with information necessary to effectively communicate with fellow members and legislative staff, and to seek support for KMA's legislative positions from members of the Kentucky General Assembly. This was followed in June with publication of the "1992 KMA Legislative Report," an overview of legislation relating to health/medical issues considered by the KGA.

There were 10 Editorial Board meetings during 1992, and of the 44 manuscripts reviewed, the editors rejected 5 and returned 3 with recommendations for revision, indicating an 82% acceptance rate. The *Journal* articles are selected for their clarity, accuracy, and clinical usefulness to the wide assortment of Kentucky physicians. Every effort is made to assure that the information presented by authors is indeed new, unique, or else so insightful as to merit publication.

The Editorial Board wishes to express appreciation to all who submitted material to *The Journal of the Kentucky Medical Association* and for the ever increasing quality of the submissions. We extend our usual invitation to all of you to submit papers, since as always, you are our reason for being. We need your support and advice — your comments, criticisms, and accolades concerning the *Journal* are being carefully reviewed and weighed.

Through obituaries, reports of notable events involving physicians across the state, and other matters of significant professional importance, the reader can stay in touch with his or her fellow state physicians. Please keep the *Journal* department apprised of these events.

We welcome your commentaries and letters to the editor on all subjects of interest to our membership, for it remains our desire to provide timely educational materials both for and by Kentucky physicians. These are challenging times — your thoughts are welcome.

For their dedication to the advancement and nurturance of the *Journal*, I want to acknowledge and thank all of the Editorial Board members: Doctors Daniel W. Varga, Scientific Editor; Stephen Z. Smith, Assistant Scientific Editor; and Jannice O. Aaron, Martha Keeney Heyburn, William P. Hoagland, and Milton F. Miller, Assistant Editors.

We thank the KMA membership and Board of Trustees for the privilege of serving you as editors.

A. Evan Overstreet, MD
Editor

Report of the Delegates to AMA

This has again been a very active year for your AMA Delegation. Just as public focus has been on health care reform, so have many of the efforts of the AMA House been directed. Each meeting sees numerous reports of committees and councils and in excess of 150 Resolutions. It is important to note the volume of material, not because of the sheer amount, but rather because it indicates an active, sometimes even tumultuous, professional reaction to the confrontations physicians must make.

The AMA House meets twice each year, where the bulk of the Delegation's efforts are directed. In December the AMA House met in Nashville and considered as one of its primary agenda items the issue of self-referral. Notwithstanding a perhaps misdirected outcry from both the public and the Congress, the House held that self-referral is appropriate if there is a demonstrated need in the community for the referral facility and alternative financing is not available, or where the facility is a direct extension of the physician's practice. To augment this position, the AMA Council on Ethical and Judicial Affairs has developed guidelines concerning ethical investments, full disclosure, and safeguards against patient exploitation. This is not a static issue, and will be reconsidered in view of further legislative pressures.

The House has continued to deal with changes to the Clinical Laboratory Improvement Act. While the intent of the Act is appropriate, modifications to make it more practical are ongoing. The AMA House has also continued to affirm its position with regard to health care reform for efforts that ensure access to care by all Americans, control rising costs, and promote self-regulation and negotiation.

In June the House of Delegates met in Chicago. This meeting was timely because of increased national efforts related to health care reform and the upcoming budget reconciliation process. At this meeting, First Lady Hillary Clinton addressed the House on the administration's health care reform activities. Mrs Clinton was candid, but not adversarial, and this meeting established a benchmark for the medical Federation's closer involvement in the administration's work. In a word, the AMA has gained a place at the reform discussion table and, since that time, a number of meetings have taken place where the discussions established by the House have been transmitted and, to a point, accepted.

AMA dues were raised by House vote to begin with an increase of $20 in 1994. This increase marks the first in five years. Ongoing consideration was given to financial incentives by health care reform plans to limit medical care, the provision of assistance to states in dealing with state-level health care reform efforts, universal employer-based insurance, global budgets, and the need for physician negotiation in health care reform efforts.

Changes to the Medicare program received intense consideration as did ongoing modifications to the Clinical Laboratory Improvement Act. As an indication of the Federation's effectiveness in influencing federal reform efforts, it was noted that the so-called "enterprise liability" thrust had been redirected. New and ongoing efforts were affirmed relating to HIV and AIDS. These included an expansion of the treatment for the heroin-addicted population to control the spread of HIV, HIV testing of victims in all rape cases, and opposition to immigration of HIV infected individuals.

The Delegation is diligent and hard-working. In addition, it is usually augmented by other officers and physician representatives of related in-state organizations. These have included officers from the Fayette and Jefferson County Medical Societies, and representatives of the Young Physicians Section, the Resident Physicians Section, and students.

Kentucky and KMA can be proud of the accomplishments of many of these individuals. Baretta Casey, MD, current President of KMA's Resident Physicians Section, has been appointed by the AMA Board of Trustees to serve on its Women in Medicine Advisory Panel. Judy Linger, MD, a psychiatry resident at the University of Kentucky, was elected as AMA-RPS Alternate Delegate to the AMA House. Ardis Hoven, MD, serves on the AMA's Group Practice Advisory Committee, and Dr Bob Goodin serves on the AMA CME Advisory Committee. Finally, but certainly not least, Esther Jansing from Owensboro was just elected as a member of the Governing Board of the AMA Alliance (formerly the Auxiliary).

Your Chair has the honor of serving as the Co-Chair of the Southeastern Delegation, which is a group of approximately 20 states who have formed a coalition within the AMA House of Delegates.

I would be remiss if I did not acknowledge the so-called "routine" work of each member of the Delegation who not only gives up two weeks practice every year, but also has become expert on particular subject areas of the House of Delegates.

Donald C. Barton, MD
Senior Delegate

Report of the Executive Vice President

In 1990, President Nelson B. Rue, MD, stated, "In the coming decade, our profession will face unprecedented challenge and change, directly affecting how we practice medicine, who will pay for our services, and whom we may or may not treat and for how long we may treat them." Dr Rue's vision of future medicine, while ominous at the time, is probably an accurate description of where politics intends to take us. The Governor's proposal for health care reform and several other legislative proposals introduced in the special session threatened to exceed Dr Rue's prediction for medicine's future. The Chair of the Board's report documents KMA's activities during the "reform process" and the report of the Committee on State Legislative Activities outlines the 1993 special session. Therefore, I won't discuss health care reform specifics in this report. However, I do think it appropriate to commend the KMA Legislative Quick Action Committee members for making extraordinary efforts to deal with this complex issue. KMA leadership had to wrestle with difficult choices, work under extremely volatile and hostile circumstances, and make on-the-spot decisions on complex issues that could affect Kentucky medicine for years to come. Representing a diverse group of patients and physicians in a political arena is not a comfortable spot to be in, especially when the outcome of those decisions affects lives and livelihoods.

First, I want to recognize President Monnig who literally gave up his practice for a year to attend countless meetings representing KMA. Dr Monnig has his ear to the ground and seeks the direction and will of the membership in framing decisions in accordance with House of Delegates action. His three terms as Chair of the Board and almost a decade of service on the Board of Trustees benefited KMA at a crucial moment in time. From a political context, Russell L. Travis, MD, was our point man, serving a unique role with his personal relationship with the Governor. While the Governor's final product met with our opposition, few people will ever appreciate the numerous and extensive changes that resulted from Dr Travis' influence and personal access to the Governor. A point man in a political conflict also becomes a lightning rod and target for critics. Dr Travis learned firsthand the rough and tumble of politics and his perseverance under adverse conditions is laudable. Unquestionably, he made outstanding contributions to KMA and his profession this year.

Ardis D. Hoven, MD, has impressed all of us with her ability to digest information, to make fair and conclusive decisions, and to relay our position to others. She was instrumental on many occasions in guiding the Quick Action Committee to a consensus. We look forward to working with Dr Hoven in the coming year, which promises to be a most difficult period as we grapple with health care reform in both a special session and the regular 1994 session. Dr Hoven will need your support, and I am confident the membership will rally around her leadership.

Dr Bill VonderHaar's political savvy, experience, and knowledge of the health care system, along with his ability to sort through complex material, helped steady the ship in the storm in which we found ourselves. In addition, he continued to carry out his time-consuming duties as KMA's Secretary-Treasurer, and we thank him for his devotion.

Special recognition goes to our old friend, Wally O. Montgomery, MD, who has led the KMA legislative effort for almost 10 years. Dr Montgomery had a very difficult year due to the illness of his wife and other personal problems, yet he remained involved and did a splendid job in guiding us through the 1993 special session. Finally, I would not want to overlook immediate Past President Dr Randy Scheen, who was with us in Frankfort and elsewhere, standing ready to provide appropriate counsel from his many years of experience.

The health care reform effort required total concentration and dedication by everyone. Staff responded as they always have in difficult circumstances, and the wealth and depth of experience made a difference. It is also appropriate to commend our outside legislative consultants, Bill Doll

and John Cooper. Their commitment to the doctors of Kentucky, advice, counsel, and hard work is appreciated.

On the federal level, we continue to work with Kentucky's Congressional delegation with the assistance of AMA in representing the physicians of Kentucky. Kentucky's Congressional delegation holds several powerful positions, and KMA is being called on to a much greater extent than before. Senator Wendell Ford, Chair of the Senate Rules and Administration Committee, and Representative William Natcher, Chair of the influential House Committee on Appropriations, are both in positions of national power. Other members of the delegation also serve on important committees, and we are in contact with them or their staff on a weekly basis. In 1993, KMA officers and staff joined with doctors throughout the US in a meeting in Washington to address health care reform. In addition, we conducted a Washington dinner for our Congressional delegation and their staff in July.

KMA membership broke all records at year-end 1992 with the largest number of Active members (3,946); the largest net gain in any year (203 more than the previous year); and the largest percentage increase in any year (5.4%). We were also pleased to accept an award from the American Medical Association for an 8% growth in AMA membership during 1992.

Our membership has continued to increase and, for the first time, we are able to report that we are 4,000+ strong in Active members for 1993. As reported last year, the intensity of health care reform debate has contributed to membership increases, but we are also concerned with the number of losses incurred this year due to members who have left the state or resigned their membership in this Association. A recruitment campaign is underway for 1994 and every member needs to be involved in strengthening our voice in these crucial times.

The joint KMA/KMIC Building Committee is in the final stages of planning for the purchase of property and preparing for the construction of a new headquarters office. As you recall, the Board of Trustees directed and the House of Delegates approved a recommendation that KMA and KMIC be housed in the same location. It was also the consensus of the Board that KMA needed an identification with a structure to enhance both the public and profession's view of the Association. We considered several options, including purchase of the existing building we rent, but the decision was made to build on a site just north of the present building on North Hurstbourne Parkway. We are in final negotiations to purchase the land, with plans to have the building ready at the end of our present lease which ends in August 1996. The purchase of land and building construction will be coordinated jointly with Kentucky Medical Insurance Company, and the building will incorporate joint usage of board and meeting rooms, along with kitchen and other facilities.

Despite the tremendous effort the legislative activities exacted on officers and staff this year, other components of KMA continued to pursue the charge and goals established by the House of Delegates. The Kentucky Physicians Care program, the vanguard of Governor Jones' Health Care Access Foundation Inc, continues to expand. The unselfish service 2,400 Kentucky physicians provide to the poor of Kentucky has not gone unnoticed. This special group of caring physicians and their staffs have provided over 50,000 patients free care, representing a total of 250,000 physician-patient encounters. We are most proud of this program and commend physicians for participating.

Kentucky Medical Insurance Company's success continues. Under the able direction of President and CEO, Steve Salman, the company retained its A.M. Best A− rating, reduced overhead, and developed new products and services for the physicians of Kentucky. Kentucky Medical Insurance Company is a tremendous asset to the practice of medicine and serves as a stabilizing influence on the cost and availability of medical malpractice insurance for Kentucky physicians. That was the major role we envisioned when we formed KMIC in 1978. We can say with confidence that KMIC has fulfilled that goal with class and respect. As we approach another cycle of increased lawsuits and outrageous awards, the strength and survival of KMIC will be critical to the practice of medicine in Kentucky. I hope you are utilizing the excellent products and services of KMIC.

KMA's oldest and best friend, the Auxiliary to KMA, changed its name in 1993 to the Kentucky Medical Association Alliance. The change in name enhances the Alliance's ability to attract members and work in lockstep with Kentucky physicians improving patient care and promoting the profession. The Alliance's role in our legislative effort and involvement on the state and local levels, often in leadership roles, bolstered KMA's efforts in the health care reform debate.

KEMPAC, the political arm of medicine, continues to grow. Despite Kentucky's relatively small physician population, Kentucky ranked 11th in 1992 among the states in the total number of PAC members. This year we are up 10% over 1992, and this success is directly tied to the hard work of the KEMPAC Board of Directors. Legislation adopted by the Kentucky General Assembly in 1992 will severely impact PACs' future involvement in state legislative races. PACs will be limited to $500 per race. Consequently, physicians on the local level will have to accept more responsibility, both personally and financially, in supporting local candidates who share their political and economic philosophies.

The Rural Kentucky Medical Scholarship Fund (RKMSF), under the leadership of Don Stephens, MD, continues to seek innovative approaches to assist rural communities and physicians. The Scholarship Fund, which has placed over 500 physicians in rural areas since 1947 and is the grandfather of all scholarship programs, established special practice grant programs to assist young physicians to locate in critical areas.

KMA's standing and ad hoc committees did an excellent job this year. Physicians who give freely of their time on these forty plus committees are the unsung heroes of the profession. We are deeply appreciative of their work.

Several changes occurred within our staff this year. We are extremely pleased to announce that David W. Carby has joined KMA staff as Director of Governmental Affairs and Staff Counsel. David was staff attorney for the Kentucky Board of Medical Licensure for seven years and previously served on the staff of the Kentucky Attorney General and the Jefferson County Attorney's office. David's knowledge of the law, and his experience with the Licensure Board, permitted him to hit the ground running and he is a welcome addition to our staff. David succeeded Brian Brezosky who left for another position. Brian was an excellent employee and we wish him well.

Occasionally, we honor staff members for particular anniversaries. I want to pay special attention to the 25th anniversary of Bill Applegate. Bill is a most dependable and knowledgeable staff member who keeps up on the latest trends in medicine, and in his position as Deputy Executive Vice President, works on a daily basis with members of the staff. Bill is an outstanding individual and is a tremendous asset to the physicians of Kentucky.

I cannot praise enough the entire staff that works for you 7 days a week, 52 weeks a year. When they have given their all, a bigger challenge arrives and they reach back and give more. They know their work; they do it well. They have no peaks and valleys . . . just peaks. I use this report to thank and compliment each of them.

The Association remains in a financially strong position. Careful planning by the Budget Committee and continued oversight of our financial operation has provided us the ability to stretch our dues dollars. Our last five-year dues plan is now expected to provide us a ten-year cycle, doubling the time it was intended when voted. Increasing income and decreasing expenditures is a daily goal.

On behalf of the KMA staff, we thank KMA members for their assistance during the past year and for the patience, understanding, and support during a difficult year. Health care reform on the federal and state levels promises to make the 1993-94 Associational year even more stressful. We believe the leadership is in place, both on the KMA and AMA levels, to meet the challenges that surely will come. I am supremely confident that if the members do their jobs, we will survive the onslaught from those who would destroy a system of medical care that serves 85% of the people well. Our task will not be easy, but if we remain vigilant and can motivate members to get involved in the political process, then we can prevail and maintain what is internationally acclaimed and nationally regarded as the finest medical system in the history of the world.

I want to thank you for the privilege of serving this Association as your CEO these past 25 years. It is an opportunity that comes to few. It has been an honor for me.

Robert G. Cox
Executive Vice President

Report of KMA Physicians Services, Inc

KMA Physicians Services, Inc, is the only wholly owned subsidiary of the Kentucky Medical Association, and serves as a holding company to its own subsidiary, the KMA Building Corporation.

The KMA Building Corporation was formed when we owned our own headquarters building. Its role was to collect rent and pay all bills relating to the most recent addition to that building, which was sold in 1991 to Hospice of Louisville, Inc.

The Building Corporation received the proceeds from the sale of the old headquarters building and transferred them to KMA's Building Fund for future use in the building of a new KMA Headquarters structure. The KMA is currently leasing space with a lease agreement lasting through 1996.

Russell L. Travis, MD
Chair

Report of the Kentucky Medical Insurance Company

Highlights — Kentucky Medical Insurance Company expects 1993 to be another milestone year. Already, highlights for the year include a reconfirmation of the company's A.M. Best rating of A− (Excellent), licensure in Ohio, and an increase in policyholders. Furthermore, the company's hospital division and all subsidiaries have reported excellent earnings for 1993.

At the same time, claims expenses have increased dramatically. Kentucky Medical predicted this harsh claims cycle, however, and is well prepared.

The company continues to look for efficiencies and has successfully reduced operating costs for 1993. Meanwhile, Kentucky Medical will continue to seek a business combination with similar medical professional liability companies.

Opportunities — For Kentucky Medical Insurance Company, the greatest opportunities are through a business combination and through subsidiary/hospital division growth. Geographic expansion will continue to be important to the company, as well as a strong focus on customer service.

Other areas of opportunities for Kentucky Medical Insurance are the "unbundling" of services. Specifically, this means marketing the company's services, such as risk management, claims handling, etc, independently.

Concerns — Even though the current claims environment was anticipated, the company is highly concerned about the rising cost of claims. Not only has the frequency of medical malpractice lawsuits increased, the severity (amount paid) has also increased.

Other concerns for Kentucky Medical Insurance include intense price competition in our market area.

Conclusion — For the balance of 1993, the business combination concept, as well as growth of the subsidiaries and hospital division, will remain high priorities.

Also, the company will continue to prepare for the worst in the claims environment. Attention will be focused on managing claims expenses and tightening the management of the litigation process.

Richard F. Hench, MD
Chair

END OF CONSENT CALENDAR ITEMS

Report of the President

I approach the end of this year with misgivings; it has been challenging, frustrating, and rewarding. It has been a year of confrontation, success, thwarted goals, and growth. I have been gratified to witness and be a part of the indomitable spirit of medicine, which carries great satisfactions and great burdens.

Health care or health system reform has dominated all of our efforts. While change is inevitable, physicians — like everyone else — experience change with suspicion, at best, and usually with a good measure of mistrust. We are trained to be in control. We are trained to observe, assess, prioritize, consider alternatives, and then take action. We are trained to create the structure and process to produce desired outcomes. We don't take offense at constructive criticism, but bristle when others interfere or disrupt our plans without consulting us.

We can't control the health system reform debate environment, and we can't maintain the status quo, but we have been adamant in demanding, and even seizing, opportunities to influence change.

Through various communications, we have tried to keep everyone up-to-date on the process that the reform debate has followed. From the original Governor's task force, through the special legislative session, at the federal level, and now through further Governor-instituted groups, we have tried to play a role on behalf of medicine, and with some good effect, I feel. While one might question the driving force of politics to preside over property and decisions, no one questions the motives for change. These are, redundantly, cost, inaccessibility to care, and the unavailability of comprehensive care to the indigent.

From a public perspective, it would seem that every group who is part of this debate is convinced that it, alone, has the correct solutions. In this venue, medicine, at first, was held to be only adversarial and, therefore, nonproductive. Grudgingly, at all levels, medicine has now become an accepted participant through the efforts of all physicians. Aside from the fact that physicians are intrinsic to the humane and compassionate welfare of society, our opinions have come to be accepted as at least as valid as any others.

While our primary role, as always, is as patient advocates, we must continuously revise our own perceptions to maintain any control over our medical destinies. To be part of the changing environment, we will have to make sacrifices in our financial security and, perhaps, individual freedoms. We must assume our role in society, not only as physicians, but as universal members, and relinquish any thoughts of control. Rather, our role must be that of counselor, guide, and statesman.

As always, physicians should be teachers, value creators, and even rule breakers, particularly when rules are made that interfere with good health care for our patients. In this role, we must carefully choose those ideas that we select to defend, but once selected, that defense should be unequivocal. Our challenge of the gross revenue tax on physicians' income is an example. At this time, the outcome of that challenge is not known, but it was undertaken in good faith and, I think, with a prominent commitment to the greater issue of financing for health care. The answer to this question, while simple, is not easy, and the isolated taxation of providers is certainly no solution.

Throughout my medical career, many dominant issues haven't changed, but rather, have intensified. As time continues, this trend will likely not attenuate. Hopefully, the part I have played this year was to help initiate and guide the proper place of physicians in change and to help direct our most democratically oriented organization. I cannot adequately describe the dedication and true commitment to our organization and its ideals that I have constantly witnessed and have been a part of. I am humbly proud to have served as your leader during this time, and have attempted through my service to honor your choice in selecting me.

William B. Monnig, MD
President

Recommendations, Reference Committee 1:
Mr Speaker, Reference Committee No. 1 reviewed the Report of the President. The Committee would like to thank Dr Monnig for the major role he has played over the past year as President, the time he has devoted to health care reform, and the true commitment he has shown to our organization for more than seventeen years.

Reference Committee No. 1 recommends that the Report of the President be filed.

Report of Kentucky Physicians Care Operating Committee

Although the Kentucky Physicians Care Operating Committee did not have a formal meeting this year, your Chair and staff have been involved in some aspect of the program on a daily basis.

Since January 1, 1985, 136,403 individuals have been certified eligible for the Kentucky Physicians Care program and 52,437 referrals have been made, which we estimate resulted in over 209,748 physician encounters. This latter figure is estimated because, in most cases, once a patient is seen by a participating physician, he or she tends to continue seeing that physi-

cian and, as a result, does not continue to call the toll free number. New applications for certified eligible patients are received in the Headquarters Office every day.

Currently, an average of 80 calls come in on the toll free line daily with inquiries and requests for referral.

The participation and support of the physicians in Kentucky continue to be excellent. Our current level of participating physicians is 2,466, representing a high percentage of the physicians who are actively practicing medicine in Kentucky. The Committee wishes to particularly recognize the continuing support of the primary care physicians who remain the initial contact point for the vast majority of referrals made through the program. The contribution made by these men and women is incalculable, and we are very appreciative of their efforts on behalf of the KPC patients and the medical profession in Kentucky.

The Kentucky Health Care Access Foundation continues as the primary funding source for the program. The Foundation underwrites the cost of the toll free telephone lines and two full-time employees. According to the Foundation, its financial contribution since the onset of the program through March 31, 1992, has been $531,308.47.

Due to space limitations at KMA Headquarters, the KPC hotline staff relocated their offices to the KMIC Headquarters Office which provides greater privacy for the hotline staff. KMIC is providing the KPC referral service space at no charge. Because of the close proximity of the KMA and KMIC Headquarters Offices, KMA continues to provide furniture, supplies, postage, computer equipment, and KMA staff involvement as needed. We are appreciative of KMIC's support of this project.

The Cabinet for Human Resources has continued to be extremely cooperative during the course of the project. Representatives from the Department for Social Insurance continue to work closely with KMA/KPC staff and provide a considerable amount of time and effort to the program, as have the 1,000 field workers in the 120 county CHR offices across the state.

Through the Kentucky Pharmacy Providers project, which began July 16, 1990, over 14,629 prescriptions have been filled at no charge to respective KPC patients. There are currently 439 pharmacies throughout the state participating in the program. We feel the support of the Kentucky Pharmacists Association and the many services provided by individual pharmacists add a much needed dimension to this program.

We particularly want to thank Pfizer/Roerig; G.D. Searle; Pratt; Iolab Corporation; Janssen Pharmaceutica, Inc; McNeil Consumer Products and Pharmaceutical; Ortho Biotech, Inc; Ortho Pharmaceutical Corporation; Abbott Laboratories; and Novo Nordisk for making their entire line of products available, at no charge, to KPC patients. The Committee is indeed grateful to these fine companies for their leadership and cooperation in making this segment of the program possible.

Currently, all Kentucky acute care hospitals participate in KHA's Fair Share program, and 370 dentists have seen 1,839 referrals since the Kentucky Dental Care project began in 1991.

The Kentucky Home Health Association also participates with its member agencies, providing five free home health visits upon referral by a participating physician. Additional visits can be made at the discretion of the home health agency.

Kentucky, through the Kentucky Physicians Care program, continues to receive national recognition for this unique program, and Kentucky's medical profession is viewed by its peers as an active, progressive leader in dealing with the issue of indigent care.

The Committee believes that the Kentucky Physicians Care program has played a role in demonstrating the needs of the medically indigent in Kentucky and the fact that the voluntary private sector is working to address those needs.

The Committee feels there are advantages to the program being on a temporary, yearly renewal basis, and, therefore, suggests that KMA continue the Kentucky Physicians Care program through December 31, 1994, contingent on:

1. Program funding being continued, as appropriate, by the Kentucky Health Care Access Foundation, with KMA contributing in-kind services as done in 1985, 1986, 1987, 1988, 1989, 1990, 1991, 1992, and 1993;
2. A continuing commitment from the Cabinet for Human Resources to evaluate program applicants for eligibility, as is currently being done;
3. The Kentucky Hospital Association continuing its Fair Share program as currently operated;
4. The Kentucky Health Care Access Foundation continuing to vigorously encourage the active participation of all other health care delivery and/or financing organizations in Kentucky Physicians Care or the Fair Share program, as may be appropriate; and
5. The Kentucky Health Care Access Foundation making Kentucky legislators aware of the plight of those ineligible for Medicaid assistance solely because they do not meet the confusing and arbitrary requirements of the Medicaid program, while working to broaden the societal financial obligation necessary to provide care to those in need of such assistance.

As Chair, I am most grateful to the many individuals and organizations that make this most significant program possible.

Russell L. Travis, MD
Chair

RECOMMENDATIONS:

1. The Committee recommends that KMA continue the Kentucky Physicians Care Program through December 31, 1994, contingent on:
 A. Program funding being continued, as appropriate, by the Kentucky Health Care Access Foundation, with KMA contributing in-kind services as done in 1985, 1986, 1987, 1988, 1989, 1990, 1991, 1992, and 1993;
 B. A continuing commitment from the Cabinet for Human Resources to evaluate program applicants for eligibility, as is currently being done;
 C. The Kentucky Hospital Association continuing its Fair Share program as currently operated;
 D. The Kentucky Health Care Access Foundation continuing to vigorously encourage the active participation of all other health care delivery and/or financing organizations in Kentucky Physicians Care or the Fair Share program, as may be appropriate; and
 E. The Kentucky Health Care Access Foundation making Kentucky legislators aware of the plight of those ineligible for Medicaid assistance solely because they do not meet the confusing and arbitrary requirements of the Medicaid program, while working to broaden the societal financial obligation necessary to provide care to those in need of such assistance.

Recommendations, Reference Committee 1:

Reference Committee No. 1 reviewed the Report of the Kentucky Physicians Care Operating Committee.

Reference Committee No. 1 recommends the adoption of the Report of the Kentucky Physicians Care Operating Committee and its recommendations.

RESOLUTION A

Freedom of Choice of Physician
Board of Trustees

WHEREAS, some currently proposed reform schemes would limit a patient's right to choose a physician by requiring participation in a pooling arrangement which would assign patients to physicians on the basis of the lowest bid; and

WHEREAS, these proposals would limit payment for services to one or two facilities in the state, thereby limiting not only location, but the physicians authorized to deliver care, even though similar services might be available to patients in their own community; and

WHEREAS, while some patients may be willing to forego freedom of choice in exchange for less expensive insurance premiums, others may not; and

WHEREAS, patients wish to choose their physician on the basis of the physician's credentials, experience, reputation, location, interpersonal skills, and other factors; now, therefore, be it

RESOLVED, that the KMA strongly support the patient's freedom of choice of physician; and be it further

RESOLVED, that KMA support and encourage a pluralistic approach to health care delivery that allows patients the option of choosing their own physician.

Recommendations, Reference Committee:
The Committee reviewed Resolution A, Freedom of Choice of Physician, submitted by the Board of Trustees.

The Committee recommends Resolution A be adopted.

RESOLUTION B

Economic Entity
Board of Trustees

WHEREAS, state and national health system reform plans based on the "managed competition model" are being discussed; and

WHEREAS, managed competition calls for large purchasing groups to contact with provider groups to provide health care to members; and

WHEREAS, organized provider groups presently exist only in urban areas of Kentucky and are traditionally driven by insurance companies or hospitals; and

WHEREAS, deep concern exists for rural and small town physicians in less populated areas of Kentucky about their ability to survive if managed competition is applied to rural areas; and

WHEREAS, hospital groups and insurance entities are taking the lead in organizing provider groups and seeking a larger role in the professional and economic components of medical practice; and

WHEREAS, KMA represents the best interest of the patient/physician relationship, regardless of the delivery/payment system; and

WHEREAS, it is appropriate that Kentucky physicians have an economic mechanism through which they can participate in payment structures which evolve from reformation of the health care delivery system; now, therefore, be it

RESOLVED, that the KMA Board of Trustees initiate a study of the feasibility of establishing a physician owned and directed economic entity which allows all qualified KMA members the opportunity to participate in delivery and payments systems evolving from state and national health system reform measures; and be it further

RESOLVED, that the Board of Trustees consider legal, professional, and financial requirements of establishing a physician owned and directed economic entity, as well as the corporate structure, philosophy, and future relationships with KMA and affiliated organizations; and be it further

RESOLVED, that the Board of Trustees, in making a study of the feasibility of establishing an economic entity may engage the services of appropriate consultants as required to help determine the advisability of such an organization, as well as levels of professional and financial support deemed necessary to assure fiscal viability; and be it further

RESOLVED, that the Board of Trustees be delegated authority to determine the feasibility of implementing an economic entity if, in its best judgement such action is warranted, with the Board making interim reports to the House of Delegates and general membership of KMA, as indicated.

Recommendations, Reference Committee 1:
Reference Committee No. 1 recommends that the first "Resolved" be amended by deleting the word "qualified" before "KMA members." The amended "Resolved" would now read:

RESOLVED, that the KMA Board of Trustees initiate a study of the feasibility of establishing a physician owned and directed economic entity which allows all ~~qualified~~ KMA members the opportunity to participate in delivery and payments systems evolving from state and national health system reform measures;

Reference Committee No. 1 recommends that Resolution B be adopted as amended.

RESOLUTION D

House Bill 1
Warren County Medical Society

WHEREAS, the Kentucky General Assembly in its Second Extraordinary Session of 1993 passed House Bill 1 with its onerous, unfair, and unconstitutional tax on health care providers and requires health care providers to submit large volumes of data to the Commonwealth at great expense to the provider and does not require the Commonwealth to ensure confidentiality with regards to the provider; now, therefore, be it

RESOLVED, that KMA pursue all legal recourse regarding all onerous aspects of House Bill 1, Second Extraordinary Session of the Kentucky General Assembly 1993.

Recommendations, Reference Committee 1:
The Committee considered Resolution D, House Bill 1, submitted by the Warren County Medical Society, and recommends the "Resolved" be amended by deleting the word "all" before "legal recourse" and the word "all" before "onerous aspects." The "Resolved" would then read:

RESOLVED, that KMA pursue ~~all~~ legal recourse regarding ~~all~~ onerous aspects of House Bill 1, Second Extraordinary Session of the Kentucky General Assembly 1993.

The Committee recommends that Resolution D be adopted as amended.

James F. Beattie, MD, Delegate from Warren County, made a motion that in lieu of the Reference Committee's recommendation, the Resolved be amended to read, "Resolved, that KMA pursue *all reasonable* legal recourse regarding *all* onerous aspects of House Bill 1, Second Extraordinary Session of the Kentucky General Assembly 1993." The motion was seconded and carried.

Resolution D, adopted as amended by the House, reads as follows:

WHEREAS, the Kentucky General Assembly in its Second Extraordinary Session of 1993 passed House Bill 1 with its onerous, unfair, and unconstitutional tax on health care providers and requires health care providers to submit large volumes of data to the Commonwealth at great expense to the provider and does not require the Commonwealth to ensure confidentiality with regards to the provider; now, therefore, be it

RESOLVED, that KMA pursue all reasonable legal recourse regarding all onerous aspects of House Bill 1, Second Extraordinary Session of the Kentucky General Assembly 1993.

RESOLUTION M

Cost Containment Subcommittee of the Health Care Reform Task Force
Legislative Committee of the Warren County Medical Society

WHEREAS, the Cost Containment Subcommittee of the Health Care Reform Task Force has endorsed a measure that would establish rate-setting and global budget for physicians and hospitals; and

WHEREAS, the Governor has stated he is in favor of this type of structure; and

WHEREAS, this also contains mandatory insurance through the state for small groups, thereby disallowing freedom of choice for citizens of Kentucky in regards to health care insurance; now, therefore, be it

RESOLVED, that the KMA go on record as being unalterably, implacably opposed to governmental rate-setting of physicians' fees, or restriction of freedom of choice by the citizens in selection of health insurance; and be it further

RESOLVED, that the KMA strongly lobby the Legislature to prevent such draconian[1] legislation being passed; and be it further

RESOLVED, that in the event this draft is passed as a bill in its present form or a similar form (espousing any rate controls, global budgets, or restriction of freedom of choice of insurance carriers), the KMA will take all legal recourse possible, up to and including petitioning the United States Supreme Court, for legal remedy from this antibusiness, individual freedom-restricting recommendation from the Cost Containment Subcommittee.

1. "Draconian: (1) Of or designating a law or code of extreme severity. (2) Exceedingly harsh; rigorous (After Draco, Athenian lawgiver of the 7th century, BC, whose laws were proverbially harsh)," *The American Heritage Dictionary, Second College Edition*, Houghton Mifflin Company, Boston, p. 422, 1982.

Addendum to Resolution M

RESOLVED, that in keeping with the Bylaws, the Board of Trustees be authorized to assess the membership any amount necessary to pursue such legal recourse in the event funds available through the KMA Legal Trust Fund are exhausted.

Recommendations, Reference Committee 1:
Reference Committee No. 1 next reviewed Resolution M, Cost Containment Subcommittee of the Health Care Reform Task Force and Addendum to Resolution M, introduced by the Legislative Committee of the Warren County Medical Society. The Committee recommends that the words, "unalterably, implacably" be deleted from the first "Resolved," and that the word "or"

be replaced with the word "and." The Committee further recommends that, in the second "Resolved," the word "draconian" be deleted and the word "from" be inserted after legislation." The Committee also recommends that the third "Resolved" and fourth "Resolved" (Addendum to Resolution M) be amended by deletion and addition so that the Resolution would read as follows:

RESOLVED, that the KMA go on record as being ~~unalterably in~~ ~~placably~~ opposed to governmental rate-setting of physicians' fees, ~~of~~ *and* restriction of freedom of choice by the citizens in selection of health insurance; and be it further

RESOLVED, that the KMA strongly lobby the Legislature to prevent such ~~draconian~~ legislation *from* being passed; and be it further

RESOLVED, that ~~in the event this draft is passed as a bill in its present form or a similar form (espousing any rate controls, global budgets, or restriction of freedom of choice of insurance carriers),~~ the KMA ~~will take~~ *consider* all legal recourse possible, up to and including petitioning the United States Supreme Court, ~~for legal remedy from this antibusiness, individual freedom restricting recommendation from the Cost Containment Subcommittee~~ *against all Health Care Reform Task Force measures in the present or future which espouse rate control, global budgets, or restrict freedom of choice of insurance carriers and physicians;* and be it further

RESOLVED, that in keeping with the Bylaws, the Board of Trustees be authorized to assess the membership ~~any~~ amounts necessary to pursue such legal recourse in the event funds available through the KMA Legal Trust Fund are exhausted.

A motion was made from the floor that the Reference Committee's recommendation in the third Resolved be modified slightly by changing the word "consider" to "pursue," and by adding the word "reasonable" before the words "legal recourse." The motion was seconded from the floor and carried.

Resolution M, adopted as amended by the Reference Committee and the House of Delegates, reads as follows:

WHEREAS, the Cost Containment Subcommittee of the Health Care Reform Task Force has endorsed a measure that would establish rate-setting and global budget for physicians and hospitals; and

WHEREAS, the Governor has stated he is in favor of this type of structure; and

WHEREAS, this also contains mandatory insurance through the state for small groups, thereby disallowing freedom of choice for citizens of Kentucky in regards to health care insurance; now, therefore, be it

RESOLVED, that the KMA go on record as being opposed to governmental rate-setting of physicians' fees, and restriction of freedom of choice by the citizens in selection of health insurance; and be it further

RESOLVED, that the KMA strongly lobby the Legislature to prevent such legislation from being passed; and be it further

RESOLVED, that the KMA pursue all reasonable legal recourse possible, up to and including petitioning the United States Supreme Court, against all Health Care Reform Task Force measures in the present or future which espouse rate control, global budgets, or restrict freedom of choice of insurance carriers and physicians; and be it further

RESOLVED, that in keeping with the Bylaws, the Board of Trustees be authorized to assess the membership amounts necessary to pursue such legal recourse in the event funds available through the KMA Legal Trust Fund are exhausted.

RESOLUTION O

Use of "EXCESS" Medicaid Funds to Balance the General Budget
Warren County Medical Society

WHEREAS, the Legislature and Administration have used $131,000,000 from the Medicaid fund to balance the general fund shortfall; and

WHEREAS, the Legislature and Administration have placed an unfair and unconstitutional tax upon physicians and hospitals for the relief of a societal problem; and

WHEREAS, the Cost Containment Subcommittee has recommended rate setting and global budgets for physicians and hospitals; now, therefore, be it

RESOLVED, that the Kentucky Medical Association is opposed to shifting Medicaid funds to balance the general budget; and be it further

RESOLVED, that the Kentucky Medical Association pursue all remedies to overturn the provider tax; and be it further

RESOLVED, that the Kentucky Medical Association work to defeat rate setting and global budgets for health care providers.

Recommendations, Reference Committee 1:
The Committee next reviewed Resolution O, Use of "*Excess*" Medicaid Funds to Balance the General Budget, submitted by Warren County Medical Society.

The Committee recommends that Resolution O be adopted.

Mr Speaker, Reference Committee No. 1 recommends the adoption of this report as a whole, as amended.

Mr Speaker, I want to thank the members of Reference Committee No. 1 who worked hard to assist the House of Delegates on these matters. Members of the Committee were: John V. Borders, MD, Lexington; Susan M. Berberich, MD, Louisville; K. Thomas Reichard, MD, Louisville; Charles G. Nichols, MD, Pikeville; and Mohan K. Rao, MD, Madisonville. I would also wish to thank Theresa Wilson for her help and guidance in preparation of this report.

Respectfully submitted,
REFERENCE COMMITTEE NO. 1
John V. Borders, MD, Lexington, Chair
Susan M. Berberich, MD, Louisville
Charles G. Nichols, MD, Pikeville
Mohan K. Rao, MD, Madisonville
K. Thomas Reichard, MD, Louisville

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF REFERENCE COMMITTEE NO. 2

G. Irene Minor, MD, Berea, Chair

13. Report of the Scientific Program Committee
14. Report of the Scientific Exhibits Committee
15. Report of the Continuing Medical Education Committee
16. Report of the Council on Continuing Medical Education
17. Report of the Cancer Committee
18. Report of the Physician Manpower Committee
19. Report of the Hospital Medical Staff Section
 Resolution G -Resident Medical Staffs in Kentucky Training Hospitals
 (Resident Physicians Section)

ITEMS FOR CONSENT

Reference Committee No. 2 reviewed the following items and recommends they be filed, by consent of the House, without discussion:

13. Report of the Scientific Program Committee — filed
14. Report of the Scientific Exhibits Committee — filed
15. Report of the Continuing Medical Education Committee — filed
16. Report of the Council on Continuing Medical Education — filed
17. Report of the Cancer Committee — filed
18. Report of the Physician Manpower Committee — filed
19. Report of the Hospital Medical Staff Section — filed

Mr Speaker, Reference Committee No. 2 recommends adoption of the Consent Calendar as a whole.

Report of the Scientific Program Committee

"Diagnosis & Management: Special Issues" was selected by the Scientific Program Committee as the overall theme for the 1993 KMA Annual Meeting Scientific Program. Each morning session will focus on the theme from the perspective of the various specialties participating in the Meeting. The Committee members and representatives from the 23 specialty societies have worked hard to bring some of this country's outstanding speakers to the Meeting, and it is hoped that the membership will find their presentations useful.

The Scientific Program was planned last fall and a meeting was held in December with the presidents and/or representatives of the 23 specialty groups that will participate in the annual session. Specialty groups' scientific programs held in conjunction with the morning general sessions have proven invaluable, and provide an excellent contribution to the continuing medical education of the membership. I personally appreciate the excellent cooperation the Committee has had from the specialty societies in planning the overall Meeting, and I thank them for their suggestions and assistance.

The 1992 Annual Meeting was held at the Hyatt Regency Hotel/Commonwealth Convention Center, with an attendance of 2,447.

Exhibitors were asked to fill out evaluation forms on Tuesday, Wednesday, and Thursday during the 1992 Meeting. This allowed a better assessment of exhibitors' viewpoints which were, overall, positive.

Results from physicians' evaluation forms were very positive and revealed that physicians attended the 1992 Annual Meeting program because of the program content.

The Kentucky Medical Group Management Association (KMGMA) will meet in conjunction with the 1993 Annual Meeting, and the Kentucky Medical Insurance Company will again sponsor a Risk Management Workshop for Office Assistants.

The 1993 KMA Annual Meeting will again be held at the Hyatt Regency Hotel/Commonwealth Convention Center in Louisville. Meetings of the KMA Board of Trustees, House of Delegates, Reference Committees, KEMPAC, and Alliance, as well as various food functions, will be held in the Hyatt Regency Hotel. General registration, specialty group meetings, general sessions, and the technical exhibit hall will be located in the Commonwealth Convention Center. We urge members and their staffs to visit the exhibits. These informal contacts offer opportunities for discussion of new products and familiarization with new equipment, free from the interruptions or distractions of the office or hospital.

There will be a slight change in the format for the general sessions this year. General scientific sessions will be held on Tuesday and Wednesday mornings, and specialty groups will meet on Tuesday and Wednesday afternoons and Thursday morning. For the past several years, attendance for the Thursday morning general session has been very low with visiting guest speakers addressing five or six people. In addition, specialty groups meeting on Thursday afternoon have voiced concern to the Committee that by the time their meetings are held, many of the exhibitors have dismantled their displays. We are hoping that these changes will address those issues. The format is being tried on a trial basis, with the results scheduled for review by the Committee when we meet this fall to plan next year's convention.

The scientific sessions are again accredited for AMA Category 1 continuing medical education credit and are also approved for CME credit by the American Academy of Family Physicians.

I am very grateful for the efforts of those who have assisted in the formation of the program, particularly the Program Committee, specialty group presidents, and program chairs. Suggestions for future programs are always welcomed by the Scientific Program Committee.

Sonia R. Teller, MD, PhD

Report of the Scientific Exhibits Committee

Although the Scientific Exhibits Committee does not meet formally, the work that is put into the scientific exhibits area adds tremendously to the overall success of the Annual Meeting. The activities of the Committee are carried out by mail and telephone. We notify members through the *Journal of the Kentucky Medical Association* and the "Communicator" of the availability of space and provide applications to interested individuals. In 1992 six scientific exhibits were approved by the Scientific Exhibits Committee. We also provide exhibit space for entities such as the Impaired Physicians Committee and the Cabinet for Human Resource. We wish to express our appreciation to the following exhibitors at the 1992 Annual Meeting:

Limb Salvage by Distal Bypass
Sibu P. Saha, MD; Anthony G. Rogers, MD; Gary F. Earle, MD; and Mario Matos, MD

Hand Tumors
Morton L. Kasdan, MD

Osteomyelitis: The Scope of the Problem
R. D. Acland, MD; D. Seligson, MD; B. Rosenberg; and S. Wilt

Five Year Follow-up Study on Chronic Pain Treatment
John Dee Tarrant, DMD
Kentucky Cancer Registry
Kentucky Cancer Program

We would also like to congratulate the exhibitors of "Limb Salvage by Distal Bypass," the recipient of the 1992 Award of Excellence.

I want to take this opportunity to thank the members of the Committee for serving. The scientific exhibits area remains an important avenue for the exchange of scientific information at the Annual Meeting, and we continue to urge all physicians to visit the scientific exhibit area.

Richard A. Kielar, MD
Chair

Report of the Continuing Medical Education Committee

The Continuing Medical Education Committee enjoyed another extremely busy year as its workload continues to increase. The Committee met formally three times and held a seminar for Committee members and Directors of Continuing Medical Education from accredited and nonaccredited facilities.

The Committee has had numerous surveys and resurveys of institutions who apply for accreditation of their CME programs. The Committee serves as the accreditation arm of KMA's CME efforts. In this role, the Committee surveys, accredits, and monitors hospitals and other facilities which then conduct their own individual CME program(s).

Survey teams were appointed for six institutions which had applied for reaccreditation. One institution's accreditation status was improved after meeting with the CME Committee and demonstrating compliance with the Essentials through extensive documentation. In addition to the resurveys of previously accredited institutions, seven new institutions applied for accreditation and were granted surveys. In the past, surveys have been done at the institution's site. In order to streamline the accreditation process, the Committee decided to perform most of the surveys on a reverse site survey basis where the institution's CME personnel will travel to the KMA Headquarters to engage in a survey. This type of survey system is encouraged by ACCME. Site surveys will still be performed, but on a case-by-case basis, determined by the Committee.

The accreditation process assumes four steps. The survey team first reviews the application; then conducts either a reverse site survey or on-site survey; and finally formulates accrediting recommendations through a survey report; this report is subsequently voted on by the Committee as a whole. The Committee then notifies the facility and informs it of its accreditation status. The Committee also requires an interim report by the accredited institution so the institution can inform the Committee of its progress between surveys.

The Committee submitted its own interim report of its activities to the Accreditation Council on Continuing Medical Education (ACCME). A portion of the KMA's own accreditation process requires that we submit an interim report between surveys as a method of monitoring our activities. The response to the interim report by the ACCME was excellent and the Committee was congratulated for its outstanding work to maintain a high level of quality CME programming in Kentucky.

The Committee continued its annual solicitation for nominees for the Educational Achievement Award. Nominations were received and candidates will be considered by the Committee. Since the Committee revised the criteria and the selection process last year, the number of nominations increased over previous years. The new criteria also standardized the selection process and allowed all nominees to be compared on an equal basis. The Educational Achievement Award will be presented at the opening session of the 1993 House of Delegates.

The Committee also underwent its own site survey by the ACCME in July. The process that KMA undergoes with the ACCME is similar to the process that local institutions undergo to be accredited by the KMA. KMA submits an application, is site-surveyed by members of the ACCME's Committee for Review and Recognition, and is informed of the accreditation status at a later date. The previous accreditation period was for three years, and the Committee is in hopes of a longer accreditation period this time since a comprehensive effort has been made to implement all ACCME suggestions for improvement. The ACCME will notify the Committee of the results of

the KMA resurvey in the fall of 1993.

Another major activity of the Committee was the issue of mandatory continuing medical education for physicians as a condition of licensure in Kentucky. Resolution J was adopted by the 1992 House of Delegates and required that physicians obtain 60 hours of continuing medical education credits over a three-year period. As recommended by Reference Committee No. 2 at the 1992 House of Delegates, the Committee was instructed to implement Resolution J. The Committee made several recommendations for advisory purposes about the mandatory requirements to the Kentucky Board of Medical Licensure which were approved by the Board of Trustees at its April 1993 meeting. The Committee suggested that the Licensure Board consider several issues in development of the regulations, including: revoking a doctor's license if he/she fails to obtain 60 hours of continuing medical education in a three-year period; allowing a six-month grace period prior to revocation of a physician's license; fining a physician $200 in addition to revocation of license for failure to comply with the requirements of mandatory CME; notifying physicians at the end of the second year of a three-year period that they are required to obtain 60 hours of continuing medical education in a three-year period; and prohibiting waivers for any instance. The Committee will continue to communicate with the Board of Medical Licensure as the regulations are implemented.

The Committee held a seminar jointly with the Council for Continuing Medical Education for CME Chairmen and Directors of Medical Education from across the state. The third annual seminar was well attended as over 60 people involved in CME listened to topics on: "The Role of the State Medical Association as Accreditor in the CME Process," "Review of the Essentials of the Continuing Medical Education Accreditation Process," "Preparing for the Reverse Site Survey," "The Standards for Commercial Support," "Sharing Ideas That Work in Managing Your CME Program," and "Essential #7: Joint Sponsorship." Ms Sue Ann Capizzi, Executive Administrator, ACCME, agreed to speak at the seminar and was very effective in informing attendees of the national perspective on the accreditation process.

The Committee also saw a change in the Chair. Larry P. Griffin, MD, who had chaired the Committee for the past four years, stepped down to take a position in Washington, DC. Dr Griffin was a valuable asset to the Committee and helped improve the Committee's relationship with the ACCME.

The Committee has an additional meeting scheduled for September and anticipates even greater activity in 1993–94.

W. David Hager, MD
Chair

Report of the Council on Continuing Medical Education

The Council on Continuing Medical Education met on two occasions this year with both meetings held jointly with the CME Committee.

The Council on Continuing Medical Education serves as the provider of CME for the Association. The main educational opportunity offered is the Annual Scientific Program. As a result of findings from the ACCME survey in 1991, the Council focused its attention on its relationship with the Annual Meeting Scientific Program Committee in order to formalize the CME planning process and maintain documentation of accredited program hours. The strengthened relationship has improved the planning and process of accredited activities that are in line with the ACCME Essentials.

The Council saw a change in Chair this year. W. David Hager, MD, who had been Chair of the Council for the past two years resigned to become the Chair of the CME Committee.

The CME Council, in conjunction with the CME Committee, sponsored a CME seminar for Committee and Council members, as well as Medical Education Directors of accredited facilities. The seminar was a great opportunity for the Committee and Council members and medical education personnel to review the Essentials of CME, which is the official method of process and organization of all CME efforts as directed by the Accreditation Council on Continuing Medical Education (ACCME). The Essentials are the basis of all sponsored CME programs throughout the country. Topics at the seminar included: "The Role of the State Medical Association as Accreditor in the CME Process," "Review of the Essentials of a Continuing Medical Education Accreditation Process," "Sharing Ideas That Work in Managing Your CME Program," "How to Prepare for a Reverse Site Survey," "Standards for Commercial Support," and "Essential 7: Joint Sponsorship." The seminar was a great opportunity to discuss aspects of continuing medical education outside of the routine committee meetings.

The Mission Statement of the Council was updated to reflect the decision of the Council to offer joint sponsorship of a professional liability insurance company's risk management seminar. The Mission Statement identifies what a sponsor of CME desires to accomplish through its overall program of CME. It describes the educational goals of the overall program in terms of content or expected learning, the physicians for whom the educational program is intended, and the general kinds of educational activities and services which will be used to accomplish these goals. The Mission Statement should be reviewed and approved on an annual basis. The change in the Mission Statement was officially approved by the Board of Trustees at its December meeting.

As mentioned previously, the Council jointly sponsors CME efforts with nonaccredited organizations. At its second meeting of the year, the Council approved joint sponsorship for a series of risk management seminars with the Kentucky Medical Insurance Company. The Council anticipates increased joint sponsorship requests in the coming year, but encourages all facilities contemplating offerings of continuing medical education to become accredited.

During the coming year, the Council will continue to work closely with the ACCME and capitalize on recommendations and suggestions of the national organization to help maintain quality continuing medical education in Kentucky.

The Council would like to thank the Board for being permitted to serve and looks forward to expanded activity in 1993–94.

James L. Borders, MD
Chair

Report of the Cancer Committee

The Cancer Committee met on one occasion this year to review and discuss current issues and concerns in the field of cancer treatment.

The Committee reviewed the current status of the Cabinet for Human Resources (CHR) program to increase screening for breast and cervical cancer for low-income women. As recommended by Reference Committee No. 2 at the KMA Annual Meeting, Michael Flynn, MD, Director of the James Graham Brown Cancer Center, was invited as a special guest to discuss the activities of its mobile van. The Brown Cancer Center mobile van provides a high volume of mammography screenings and is seen as an effective model for identifying and researching problems that may exist for such issues as funding for mammography screenings, access to screenings for women, why women fail to get screened, and factors that affect the cost of a screening. Discussion at the legislative level regarding health care reform also prompted the Committee to assess mammography screening expenses.

The Brown Cancer Center mobile van targets areas accessible to the public to improve access for women. The van travels to shopping malls, corporate settings, and public health departments. The Committee studied the various reasons why women fail to receive screenings. Many are uneducated about the screening process and others do not want to take the time out of work when the van comes to their company. Even though the mobile van performs a high number of screenings, the Brown Cancer Center's budget for the van is in the red, and the Center recently had to increase its charge for a mammography screening to cover costs to run the van. A Massachusetts study was cited that indicated at least 28 screenings per day must be done to allow for a cost of $50 per woman in order to cover the costs of the screenings.

The Committee also discussed the Breast Cancer Screening Program and Fund. The goal of the program is to educate indigent women in Kentucky about breast cancer and the availability of mammograms at affordable rates. The fund offers a subsidy to the program which allows the health departments to perform mammograms at $50 for indigent women.

Since the program began in 1990, 10,000 mammographies have been done annually. Currently, over 90 facilities have contracted with the Department for Health Services and their local health department to provide screenings. A list of accredited facilities was distributed to the Committee

for review. Facilities that contract through the health departments are required to become accredited by the American College of Radiology within a year of the contract date. As recommended by Reference Committee No. 2 at the 1992 House of Delegates, the Committee published an article in the "Communicator" and recommended that a follow-up article be written to make physicians aware of the program and the fact that a subsidy is available through the local health departments for mammography screenings. A request was also made to survey radiologists to determine the screening practices and the reporting of results. The Committee agreed to work with the Cancer Control Program of the Department for Health Services and perform a survey on mammography screening practices.

As recommended by Reference Committee No. 2 at the 1992 Annual Meeting, a member of the Kentucky Chapter, American College of Radiology was invited to report at the meeting. Larry Wilson, MD, representative of the Kentucky Chapter, American College of Radiology, was invited to discuss the policy that was adopted at the Kentucky College of Radiology's Annual Meeting dealing with screening mammography. Dr Wilson reported that the policy encompassed the following:

> The Kentucky Chapter of the American College of Radiology endorses participation in and encourages its members to support screening mammography for all women throughout the Commonwealth in accordance with American Cancer Society guidelines. The Chapter encourages all Kentucky radiologists and hospitals to participate in such mammography screening programs adhering to ACR Standards.
>
> The Chapter also encourages members to provide screening mammography at a reasonable cost for all women in Kentucky.
>
> The Chapter commends those many radiologists and hospitals already participating in such programs.

The Committee discussed the results of its cervical cancer survey sent to family physicians, OB/GYNs, and general practitioners regarding detection and treatment of cervical cancer. The survey was conducted with the assistance of Tom Day, MD, and Gil Friedell, MD. Dr Day reported that some of the results of the survey were unexpected and indicated that some of the questions may have been unclear. Nevertheless, a complete analysis of the results will be performed. It was recommended that the results should constitute an article in the "Communicator" or *Journal* in order to help educate physicians on cervical cancer treatment.

The Committee looks forward to expanded activity in 1993–94. We thank the KMA Board of Trustees for being permitted to serve and urge members to refer relevant concerns to the Committee.

Clinton C. Cook, III, MD
Chair

Report of the Physician Manpower Committee

The Physician Manpower Committee met on one occasion this year to review issues relating to primary care and to discuss the maldistribution problem of physicians in the state. With considerable discussion of health care reform proposals on the state level, the Committee reviewed the current state of the distribution of physicians in Kentucky, discussed the initiatives already underway to recruit and encourage physicians to locate in rural and underserved inner city areas, and assessed and prioritized initiatives that could further alleviate the problem and best serve those areas in need of physicians. The broad representation of physicians, medical school admissions staff, physician placement service staff, and representatives from the Cabinet for Human Resources who attended the meeting demonstrated that the maldistribution of physicians is a growing concern and should be addressed and brought to a consensus through a unified voice.

The factors most important in primary care physician choice of specialty and location of practice are multiple, but generally can be related to lifestyle factors, reimbursement factors, and low prestige for the primary care physician.

Many of the initiatives discussed by the Committee will require time to have a significant impact, and yet it would appear that our Governor and the state legislature will move ahead aggressively in several areas of health care reform. The medical community should strongly oppose any initiatives that require a specific quota of students and/or residents positions, and also oppose any initiatives that jeopardize the quality of health care provided to our patients. Needless to say, a great number of negotiations and compromises will be required, but it is important that we have as our primary objective the protection of high quality health care, access to that high quality care, and provision of that care by qualified physicians at an affordable cost. The best interests of the profession as a whole must take precedence over individual priorities. It is the intent of the Committee to further pursue these issues at future Committee meetings.

The Committee has also been active in other areas as well. One issue of importance identified by the Committee to increase the number of rural physicians is to target high school students and discuss with them the possibilities of medical school. Many rural students dream of attending medical school but for one reason or another think that it is impossible. The Committee has taken an active role in contacting physicians in rural areas and encouraging them to speak at a local high school about medicine as a career. To give a medical school perspective to the high school students, the medical school student representatives on the Committee were active in contacting fellow classmates to join the local physician in the presentation to the high school students. The number of presentations increased this year, and we look forward to more presentations in the years to come.

Other activities by the Committee included implementation of Resolution E and Resolution K from the 1992 House of Delegates. From the Report of Reference Committee No. 2, Resolution E urged the Committee to work with the medical schools and the primary care specialty groups to help coordinate entry of medical students into primary care preceptorships prior to the third year of study. This issue had been discussed at past committee meetings and in discussing the issue with the medical schools, the Committee felt the best solution would be to alert physicians around the state to the successful preceptorships already taking place through the medical schools and different primary care specialty groups. An article was published in the "Communicator" announcing to the KMA membership that all primary care physicians are encouraged to contact the medical schools in order to sponsor medical school students for preceptorships.

From the Report of Reference Committee No. 2 at the 1992 House of Delegates meeting, Resolution K, Survey of Physicians Who Leave Kentucky, asked the Committee to contact the Cabinet for Human Resources and the medical schools to determine if information required in the Resolution already existed, and if not, ask the Cabinet for Human Resources to conduct a study. After researching the issue and discovering that no information as specified in the Resolution exists, the Cabinet for Human Resources was contacted and asked to do a survey. The Cabinet for Human Resources has agreed to perform the survey and members of the Committee have met with staff of CHR to work out the details of the survey. We expect this to be an ongoing effort and the results are expected to give the Committee insight into possible incentives that can be offered to keep our medical school students in Kentucky after they receive training.

We thank the KMA Board of Trustees for being permitted to serve.

Robert R. Goodin, MD
Chair

Recommendations:

1. The Committee recommends that the Kentucky Medical Association should oppose initiatives that require a specific quota of students and/or resident positions, and also oppose any initiatives that jeopardize the quality of health care provided to patients.

Report of the Hospital Medical Staff Section

The Hospital Medical Staff Section (HMSS), established in 1984 to provide a forum for discussion of mutual problems of hospital medical staffs, continues to see increased participation by hospital medical staff representatives in activities of the Section.

The HMSS Steering Committee works toward planning educational programs each year that will include information for physicians that is vital to their individual practices and their function as members of the medical staff of their hospitals. The Committee met in March to discuss the 1993 annual meeting of the Section and how the HMSS could be more helpful to medical staffs. It was decided at that time to have the annual meeting during the fall.

The Committee was privileged to have William B. Monnig, MD, KMA President and Founding Chair of the KMA-HMSS, in attendance at the March meeting. Dr Monnig shared his belief that hospital medical staffs are going to be the grassroots organization in dealing with regional health care net-

works at both the national and state levels. With everyone trying to develop an organization to take care of patients from the time they enter the health care system until they are healthy, at an all-inclusive charge, the medical staff can be an effective entity to represent doctors' interests. This is a great opportunity, but to do this medical staffs must be well organized.

Hospital/medical staff future relationships may not be as "friendly" as they have been in the past. In 1994 there will be a halt to JCAHO's protection of medical staffs to which physicians have become accustomed. JCAHO is rewriting all its manuals and standards, and the tone of those will show less favor to medical staffs. It is extremely important for medical staffs to have good, all-inclusive bylaws to protect physicians' rights in the hospital setting.

It is also important that medical staffs have good relationships with their hospitals. The KMA-HMSS has available a 52-page document, "Guidelines for Hospital Medical Staff Bylaws," published in August 1992. Prepared by KMA's outside legal counsel, this document is available at no charge to KMA members.

Most reform initiatives propose the regional delivery of medical care, and the obvious modality for implementation is medical staffs and hospitals working together. The risk exists, however, for hospitals to assume the corporate practice of medicine. It is extremely important to look at protecting the right of each member of the medical staff as he or she practices in the hospital setting. This makes the need even greater for more hospital medical staffs to become involved in the HMSS at the state and national levels. Both Hospital Medical Staff Sections can be excellent sources for needed information and assistance.

The HMSS firmly believes it should maintain an educational direction to help medical staffs cope with changes in the health care delivery system. As part of that educational direction, the HMSS cosponsored with the KMA Committee on State Legislative Activities a special Legislative Seminar on Health Care Reform on May 19, 1993. Attendance at this Seminar included KMA-HMSS representatives, hospital medical staff presidents, hospital administrators, and hospital board chairmen, as well as KMA leadership and legislative key contacts. The main thrust of that meeting was health care reform with the latest available information being presented to participants. Without doubt, health care reform will involve a managed care approach to the practice of medicine.

Several KMA-HMSS members attended the AMA-HMSS meeting in June. During that meeting, the AMA-HMSS highlighted managed care with a program it has developed called "Medicine in Transition: Managing Change in a New Environment," which is an extensive tool designed to educate AMA members about managed care and its impact on their practices. This appears to be an excellent program with five components:

1. A series of books and videotapes that provide practical information about managed care, including an in-depth understanding of physicians' rights and options and how managed care works, and explains the legal implications of managed care and contract negotiations — Doctors Resource Service (DRS);
2. American Medical Television broadcasts on managed care to include personal interviews with physicians who have excelled in the managed care environment and national managed care experts;
3. A national network of legal and business managed care experts to provide affordable "hands-on" services to AMA members as they respond to members' needs to identify physician-friendly advocates. The network will include physicians who will provide peer-to-peer consultations to allow members to avoid pitfalls that others have overcome and will stimulate creative solutions;
4. A series of managed care workshops that can be taken around the country emphasizing practical approaches to the challenges of managed care;
5. The hiring of AMA of an in-house attorney with extensive managed care expertise to head up AMA's managed care initiatives.

During the KMA Annual Meeting in September, the HMSS will be participating in the KMA Membership Booth located in the health education area of the exhibit hall. Plan to stop to learn more about KMA and AMA Hospital Medical Staff Section activities.

The KMA-HMSS Steering Committee will be meeting again on August 26 to plan the annual meeting of the Section to be held in late October or early November. We hope by that time to have more definite information on Governor Jones' health care reform plan and health care reform at the national level. The program will include as much pertinent information on the current situation as possible, and we hope to also provide expertise from the local community which will help medical staffs deal with managed care situations as part of the health care reform initiatives. We are also hoping to have some predictions on what a medical staff might be like two years from now with health care reform measures in place.

During the business portion of the HMSS annual meeting, three positions on the Steering Committee will be filled by election — the Secretary and two members at large. The HMSS Nominating Committee will propose names for these three-year positions, and nominations will also be accepted from the floor. Steering Committee members holding other positions will remain on the Committee filling unexpired terms.

The Steering Committee would like to thank William D. Pratt, MD, London, Chair, and the other members of the 1992–93 HMSS Nominating Committee, for their dedicated work in selecting candidates for these positions. Other members of the Nominating Committee were William Albert, MD, Russellville; Rex Cox, MD, Louisville; John D. Jefferies, MD, Owensboro; and Madonna Ringswald, DO, LaGrange.

Names being proposed by the Steering Committee for election by the Section as the 1993–94 HMSS Nominating Committee are John D. O'Brien, MD, Louisville; Kenneth E. Green, MD, Leitchfield; William D. Pratt, MD, London; H. Michael Oghia, MD, Russell Springs; and Robert J. Emslie, MD, Bowling Green.

As Chairman of the KMA Hospital Medical Staff Section, I would like to take this opportunity to express appreciation to the medical staffs and Section representatives of those hospitals who have chosen to participate in the KMA-HMSS. I am also grateful for the dedication of the members of the 1992–93 Steering Committee for their efforts to make the HMSS an effective KMA activity. Those members are Kenneth E. Green, MD, Leitchfield, Vice Chair; Rex Cox, MD, Louisville, Secretary; William D. Pratt, MD, London, Delegate; H. Michael Oghia, MD, Russell Springs, Alternate Delegate; and Robert Emslie, MD, Bowling Green, and William O'Bryan, MD, Owensboro, Members at Large.

The HMSS will continue working toward its goal of having active participation from the medical staff of each eligible hospital in Kentucky and providing whatever assistance it can to medical staff members. This is a positive step toward assuring good working relationships between physicians and hospitals, and I urge each physician to see that the medical staff of his or her hospital becomes actively involved in the KMA or AMA Hospital Medical Staff Sections.

John D. O'Brien, MD
Chair

END OF CONSENT CALENDAR ITEMS

RESOLUTION G

Resident Medical Staffs in Kentucky Training Hospitals
KMA Resident Physicians Section

WHEREAS, the development of resident medical staff membership within the hospital medical staff would assist in the organization of a liaison between the hospital's medical staff and its residents so that the resident medical staff may advise the hospital medical staff about the quality of patient care provided by residents; and

WHEREAS, such a liaison provides an effective training ground in medical staff affairs for residents and establishes leadership skills; and

WHEREAS, the AMA House of Delegates at its 1993 Annual Meeting adopted a Resolution calling for the AMA and AMA-RPS to work with state medical societies, state resident physicians sections, and state hospital medical staff sections in establishing resident medical staffs in all US training hospitals; now, therefore, be it

RESOLVED, that the Kentucky Medical Association ask the KMA Hospital Medical Staff Section to work with the KMA-RPS in addressing the goal of establishing resident medical staffs in all Kentucky training hospitals.

Recommendations, Reference Committee 2:
Reference Committee No. 2 considered Resolution G, Resident Medical Staffs in Kentucky Training Hospitals (Resident Physicians Section), introduced by the KMA Resident Physicians Section.

Reference Committee No. 2 recommends that Resolution G be adopted.

Reference Committee No. 2 would like to commend the work of the Committees.

Reference Committee No. 2 feels that all physicians would benefit from participation in the Hospital Medical Staff Section, encourages all members to become active, and would urge everyone to attend the next meeting of the Hospital Medical Staff on November 18 at the Alliant Health Pavilion.

Mr Speaker, Reference Committee No. 2 recommends adoption of the report of Reference Committee No. 2 as a whole.

Mr Speaker, I would like to thank the other members of the Committee: James F. Beattie, Jr, MD, Bowling Green; H. Michael Oghia, MD, Russell Springs; William D. Pratt, MD, London; and Thomas K. Slabaugh, MD, Lexington. I also want to personally thank Beth Thomas for her assistance in the preparation of this report.

Respectfully submitted,
REFERENCE COMMITTEE NO. 2
G. Irene Minor, MD, Berea, Chair
James F. Beattie, Jr, MD, Bowling Green
H. Michael Oghia, MD, Russell Springs
William D. Pratt, MD, London
Thomas K. Slabaugh, MD, Lexington

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF CONFERENCE COMMITTEE NO. 3

Beverly M. Gaines, MD, Louisville, Chair

20. Report of the Maternal Mortality Study Committee
21. Report of the Committee on National Legislative Activities
22. Report of the Committee on State Legislative Activities
23. Report of the Committee on Professional Liability Insurance
24. Report of the Committee on Impaired Physicians
25. Report of the Committee on Care for the Elderly

5. Report of the Chairman, Board of Trustees, Report of the Ad Hoc Committee to Implement Resolution M (1991) (Do Not Resuscitate) *only*

Resolution C — Physician Assistants (McCracken County Medical Society)

Resolution I — Nursing Home Regulations (Jefferson County Medical Society)

Resolution L — Proposed Nerve Gas Incinerator (Madison County Medical Society)

Resolution N — Nursing Home Beds (Pulaski County Medical Society)

Report of the Maternal Mortality Study Committee

The Maternal Mortality Study Committee of the Kentucky Medical Association met once during the organizational year, September 15, 1992. Only two cases were available for study. Considerable detailed discussion took place among the Committee about these two complicated situations. After extensive review, the following classifications were made.

MATERNAL MORTALITY STUDY TABLE

Obstetric Indirect	Contributing Factor Sickle Cell Anemia
Obstetric Direct	Death from intraoperative blood loss — Contributing factor Placenta Previa

Accompanying this report is a table giving numbers of our ongoing analysis of maternal mortality for Kentucky since 1960. Publication is planned, but we are still verifying certain recent cases. It is gratifying that we have a declining number of Direct Obstetric Preventable deaths. Certain cases are listed as "unknown" mainly because of the inability to obtain complete information. What information we do have would indicate they are Indirect Obstetrical deaths; that is, the woman was found to be pregnant but died as a result of an automobile accident or other circumstance not directly involving the pregnancy.

Two maternal mortality cases were published in the *Journal of the Kentucky Medical Association*, one in October 1992 and the other in February 1993.

We are indebted to the diligent efforts of John Petry, MD, for his significant contribution in finding and preparing cases for the Study Committee. The work of Elizabeth Price is to be acknowledged in her efforts in tabulating data.

John W. Greene, Jr, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the report of the Maternal Mortality Study Committee and commends the committee and its Chairman, John W. Greene, Jr, MD, for its work.

Reference Committee No. 3 recommends the Report of the Maternal Mortality Study Committee be filed.

Report of the Committee on National Legislative Activities

KMA's national legislative activities were intense this year, even though there were few major issues. The significance of these issues more than made up for their small numbers.

The current Congress has the highest number of new members in history. This changing face of Congress mirrors the redirection of the political/economic process and, most likely, the views of the populace. In Kentucky, Democrat Tom Barlow defeated long-term Congressman Carroll Hubbard. In the Sixth District, former Lexington Mayor Scotty Baesler became the Congressman in a newly defined district, and Congressman Hal Rogers faced representing a district also changed based on data from the 1990 Census. Early on KMA, together with a representative of the AMA Washington Office, met with Congressman Baesler to establish a philosophical discussion, and it is hoped that this early contact will prove to be fruitful.

At the beginning of this Congressional session, organized medicine's goals were to play a role in health system reform, to seek tort reform as part of any changes, to seek to revise requirements of the Clinical Laboratory Improvement Act of 1988, to influence positive changes to the Medicare Program, and to continue monitoring development of any changes in OSHA regulations.

Health system reform was the overwhelming focus of the new Congress. In March KMA officers and staff met with Kentucky's Congressional Delegation in Washington to offer initial views and opinions about health system reform based on the AMA's Health Access America program and similar efforts being undertaken at the time in Kentucky. Early on, organized medicine was excluded from the health system reform talks. Since First Lady Hillary Rodham Clinton's Task Force has completed its work, however, organized medicine, through AMA, has enjoyed a number of meetings with top federal staff as well as Mrs Clinton on health system reform issues. As in Kentucky, the major points of discussion relating to health system reform are price freezes and controls, universal coverage issues, and fiscal resources.

During the year, contact was maintained routinely with Kentucky's Congressmen on various issues of health system reform, but as the first session began to draw to a close, budget reconciliation matters became more urgent. The Congressional Budget Resolution called for a $500 billion deficit reduction. An obvious target for reduction was health care spending, primarily in the Medicare Program.

In late July, physicians, spouses, and staff again visited Washington to meet with Kentucky's Congressmen to reinforce earlier communication relating to budget cuts and health system reform. This Washington visitation and dinner was scheduled much later than usual for the sole purpose of making personal visits as constituents during a critical time. In addition to a concern over Medicare cuts, KMA's representatives were likewise concerned that health system reform issues might be included as portions of the budget bill, and thereby not subject to discussion as separate matters. Obviously, the Medicare Program was particularly vulnerable to the budget reconciliation process, and proposed cuts would obviate Medicare cost control efforts

previously agreed to by the Congress and organized medicine.

At the time of the Washington visit, a Conference Committee had been convened to reconcile budget differences between the two Houses of Congress. As of the time of this writing, the Conference Committee has completed its work, and the House of Representatives has approved the Conference Committee report by a very close margin.

The budget reconciliation package calls for a deficit reduction of approximately $496 billion over the next five years, of which $56 billion will be reduced from Medicare spending. While this is a significant amount of money, of the $56 billion, only approximately $11 billion will be cut from physician reimbursement over the next five years.

This reduction will be accomplished by reducing Medicare payment schedule updates. The formula used to determine "payment update" reductions would be based on the Medical Economic Index, the Medicare Volume Performance Standards rule, and the practice expense component of the RBRVS.

Medical Economic Index increases are estimated to be on the order of 2.4% per year. The Medicare Volume Performance Standard updates are predicted on an absence of increase of utilization of services. In other words, if the volume of Medicare services performed exceeds the standards for one year, no updates will be made for the succeeding year. The practice expense component of the RBRVS will be reduced by 25% a year over the next three years if practice expenses exceed the total payment update.

Overall, payment updates for 1994 will be an 8.6% increase for surgical services, a 6.6% increase for primary care, and 4% increase for "other nonsurgeries." In 1995, the updates for surgical and nonsurgical services will be reduced by 2.7%, but there will be no reduction in primary care updates from the second-year cut. This will be done presumably to achieve more parity between surgical and primary care payments.

At the present time, the budget reconciliation bill contains the so-called "anti-hassle II" provisions vetoed by President Bush last year. These include payment for EKG interpretations done in the office and no reduction in payment for new physicians in their first four years of practice.

The reconciliation package also addresses physician ownership and self-referral issues. The ban on referral of patients to laboratories where the referring physician has an ownership interest would be extended to therapy services, outpatient drugs, and durable medical equipment. There will be exemptions for physicians who share facilities that are not part of a formal group arrangement and an exemption based on community need where alternative financing is not available. The self-referral ban would not apply to group practices where each physician in the group provides the full range of lab services that all group members do; where amounts billed for lab services are treated as receipts of the whole group; where overhead expenses are equally shared and no member of the group receives compensation based on the volume of referrals; and where all members of the group, together, personally perform at least 75% of the services ordered.

During the final days of the first session, KMA also made contacts to encourage the confirmation of Joycelyn Elders for the position of Surgeon General. Dr Elders, who has enjoyed a notable career in public health, particularly in Arkansas, has been endorsed by the AMA. It was felt that delay of her confirmation may have related to organized medicine's strong involvement in trying to influence the budget process.

Although health system reform will continue to occupy a good deal of Congressional focus, the consensus that the Committee has perceived from its Washington contacts is that no substantive changes are likely to occur until 1995. The Committee will continue to closely monitor these activities and appreciates the support and efforts of the membership and the Board of Trustees.

Donald C. Barton, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the report of the Committee on National Legislative Activities and thanks the committee for its work. The Reference Committee commends the Committee on National Legislative Activities and its Chairman, Donald C. Barton, MD, for its endeavors.

Reference Committee No. 3 recommends that the Report of the Committee on National Legislative Activities be filed.

Report of the Committee on State Legislative Activities

Following are "summaries" of Resolutions and Recommendations adopted by the 1992 House and Delegates and referred to the Committee on State Legislative Activities:

Resolution B — Health Care Reform, reaffirming House of Delegates policy regarding coordination of state legislative activities.

Resolution D — Deleterious Effects of Tobacco Use, encouraging the Kentucky General Assembly to increase its attention to the serious health problems of tobacco product use and the trend of teenage smoking.

Resolution L — Mandated Services Requirements for Kentucky-Trained Physicians, opposing any legislative proposals that institute an involuntary service requirement for physicians trained in Kentucky.

Resolution O — Excise Tax on Tobacco Products and Discounts for Nonsmokers, directing KMA to work toward the passage of an increased excise tax on the sale of cigarettes to the national median to raise funds for health care in Kentucky.

Resolution P — Restrictions on Smoking, directing KMA to support certain legislative issues concerning tobacco use.

Resolution R — ARNP Prescribing Privileges, directing KMA to support the joint collaborative practice of physicians and ARNPs under written protocol.

Recommendation of the Report of the Chairman, Board of Trustees, reaffirming KMA policy that physicians offices should be exempt from CON except for equipment costing in excess of $250,000.

Recommendation of the Report of the Committee to Investigate Changing Trends in Medicine, recommending that KMA consider the feasibility of legislative support for requiring advance directives to be made by everyone in Kentucky over a certain age, eg, 40 years.

These policies have been filed and will serve as guidance for KMA as it considers legislation relating to these particular issues.

At the only scheduled meeting of the Committee, William B. Monnig, MD, President, and Russell L. Travis, MD, Chairman, Board of Trustees, addressed the Committee regarding the Governor's proposal to reform Kentucky's health care system and assured members that KMA leadership and staff have studied the plans carefully and thoroughly. Committee members were informed that their influence on health care reform can best be pursued through their local legislators and that they should keep in touch with their legislators and serve as a source of information for the Special Legislative Session on Health Care Reform. Each section of the governor's latest proposal was reviewed with Committee members. Emphasis was placed on the Health Care Authority, provider tax, and tort reform.

The Governor had promised to call the Kentucky General Assembly (KGA) into session in October 1992. Due to lack of support from members of the KGA, the date was continually delayed. On May 10, 1993, the Governor called the Kentucky General Assembly into special session to deal with health care reform. The Governor's proposal was a broad-based effort to provide universal access for all Kentuckians, financed by a provider tax and a 3.75% tax on all employers. The bill, as reported, would have clamped price controls on all providers, established a powerful health care authority, and placed strong managerial control over the health care industry. Managed care, utilizing the gatekeeper concept, was a major component and controlling aspect of the Governor's plan. Arbitration and mediation with vague promises of additional tort reform in 1994 were cornerstones of the liability reform mechanisms of the legislation.

It was obvious from the beginning that General Assembly members were in the same dilemma as the rest of the nation in determining how to reform health care. Powerful pressure from small business groups torpedoed any chance the Governor had in enacting the employer tax. Posturing from the administrative and legislative leadership over what truly constituted health care reform and how far it should go dominated the early days of the session. We became deeply concerned as the KGA moved toward supporting reducing costs as a politically expedient method to appease the public. KMA became the first group to favor postponing reform until some consensus could be reached. On May 27, the leadership of KGA elected to pass the provider tax and adjourn. The following health care bills were introduced:

- HB 1, the provider tax, was the only health reform legislation adopted.
- HB 3, recognized overhead costs in establishing reimbursement rates for physicians (adopted as an amendment to HB 1).

- HB 4, the Governor's health care reform plan.
- HB 5, health care reform proposal introduced by Representative Ernesto Scorsone.
- HB 7, introduced by House Republicans, called for a voucher-type system, relying upon tobacco and sales taxes to fund indigent care.

On the Senate side:

- SB 1, Mike Moloney introduced another version of the Governor's plan.
- SB 3, introduced by Benny Ray Bailey, might be called "the Governor's bill in another bottle."
- SB 4, introduced by Senator Dick Roeding, recommended the privatization of Medicaid.
- SB 6, introduced by the Senate Republican leadership, did not include a tax on employers nor did it call for a powerful health care authority. It did call for strong tort reform measures.

KMA strongly supported increases in the tobacco tax to fund health care for the indigent. We testified on several occasions, as did other groups, on the need for increased taxes on tobacco. We were beginning to detect some movement within the General Assembly to support increased taxes on tobacco; however, the Clinton administration proposal supporting a $2.00 tax increase per cigarette pack blunted any serious efforts to achieve success in Kentucky.

Price controls appear to be the major theme of subsequent special or regular sessions of the Kentucky General Assembly dealing with health care reform. The state budget is in crisis and either deep cuts or massive tax increases will be required to keep the state afloat. Consequently, it will be extremely difficult for the KGA to increase taxes and tax employers to fund universal health care. Price controls on hospital and doctors play well with the media and the public and divert attention from the real issues of rising health costs. Don't be surprised if the present provider tax rate is the target for a hefty increase by future sessions.

The leadership of KMA was not only disappointed but puzzled at the lack of political activity by Kentucky physicians during the special session. Other than opposition to the tax, we saw little evidence of political contact between physicians and legislators. Physicians need to be especially concerned with the powers of the health care authority and its ability to establish reimbursement; collect and disseminate data; and determine where, what, when, and how medicine is practiced.

Some of the proposals could be calamitous to the practice of medicine and delivery of health care in this state. Kentucky is being labeled as "doctor unfriendly" as a result of the 2% provider tax and continuous media doctor-bashing won't alleviate that perception among new physicians looking for a place to practice. Health care delivery in Kentucky is much more fragile than bureaucrats and politicians would like to admit. We have an aging primary care physician base, especially in the rural areas of Kentucky and, if threatened, many of these physicians will opt for early retirement or reduction in the number of patients they see.

Let me urge you to get involved as you have never done before. Your participation is crucial if we are to be major players in how health care is delivered in Kentucky.

The KMA membership owes a debt of gratitude to our President, William B. Monnig, MD, who has spent countless hours on the road and in conferences representing us. Bill's year was to have been a nonlegislative year, but proved to be so different. He rose to the challenge and represented us well with all his efforts.

The same tribute can be made to Russell L. Travis, MD, Chairman of the Board of Trustees. His expert knowledge of indigent care and his association with the Governor and legislative leaders were of considerable value during 1992-93.

Mr Don Chasteen has proven to be an expert lobbyist and of inestimable value to KMA as he leads the legislative team in Frankfort. He and his coworkers and the entire KMA administrative staff have represented us well this year.

Thank you for the opportunity to serve, for your personal interest, and the support you provide to our legislative efforts.

Wally O. Montgomery, MD
Chairman

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the report of the Committee on State Legislative Activities and thanks the committee for its report. The Reference Committee commends the Committee on State Legislative Activities and its Chairman, Wally O. Montgomery, MD, for its tireless efforts and hard work and encourages the KMA membership to support this committee during the upcoming session of the Kentucky General Assembly as health care reform has become a high priority for physicians today.

Reference Committee No. 3 recommends the Report of the Committee on State Legislative Activities be filed.

Report of the Committee on Professional Liability Insurance

The Committee on Professional Liability Insurance met on several occasions, both formally and informally, to address issues relating to tort reform. The KMA House of Delegates previously established the following primary goals for tort reform:

1. An amendment to Section 54 of the Kentucky Constitution that would permit the Kentucky General Assembly to place limitations on noneconomic awards (ie, pain, suffering, loss of consortium).
2. The implementation of a patient compensation plan modeled after the Workers' Compensation system.

We have consistently worked toward these goals, along with other proposals, to address the waste in the present civil justice system.

During the Special Session on Health Care Reform, we emphasized the need for reforming our legal system. We testified on three occasions, promoting the need for tort reform.

At the request of the Interim Joint Committee on Health and Welfare, we provided extensive information containing reports generated by KMA and others detailing costs associated with professional liability insurance and defensive medicine.

In addition, supplemental supporting information on PLI was included in KMA's testimony during the Special Session on Health Care Reform. In February, William E. Doll, Jr, KMA legislative consultant, testified before the Health Care Commission. In a written 20-page brief, Mr Doll concluded, "No single change or measure will be a cure to the problems which warrant 'health care reform.' But to approach reform without recognizing pressures generated by our civil justice system is a mistake."

In August 1992 the KMA Committee on Maternal and Child Health surveyed over 1,000 family practitioners and obstetricians. A more detailed conclusion of that report is included in the Committee on Maternal and Child Health's report to the House of Delegates. The summation of that data and the full report is scheduled to be published in the September issue of the *Journal of the Kentucky Medical Association*. The Committee on PLI authorized the University of Kentucky Research Studies Office to analyze the results of the survey of obstetrical care providers in the state. The Committee on Maternal and Child Health received a healthy 436 responses to its survey.

In summarizing the survey, the UK Research Studies Office noted, "Among those who are or might be practicing OB, reform of the current liability regulations (law) is the single most important thing cited that might enable or persuade these doctors to resume or continue their OB practice." Of all respondents to the survey, 23% had experienced an obstetrical-related lawsuit. According to those responses, 44.2% of those currently practicing obstetrics had been sued. Only 12.3% of those no longer practicing OB indicated that they had been sued.

This survey confirms the results of a survey KMA authorized in 1987 in which we canvassed the public, hospital administrators, and physicians to determine their attitudes on liability insurance. All three groups overwhelmingly supported efforts to reform the system and supported KMA's recommendations to amend the Constitution.

In addition to the obstetrical survey, the PLI Committee authorized a public relations campaign related to liability insurance and health care reform. This effort included brochures and holders for use in all Kentucky physicians' offices. We also developed a detailed and professional packet outlining the KMA Plan for Health Care Reform. That packet was delivered to every legislator, members of the Governor's Task Force on Health Care Access and Affordability, members of the Governor's Commission for Health Care Reform, KMA Key Contact physicians, and other groups. Both projects emphasized the priority of reforming Kentucky's legal system.

We have been extremely pleased, and quite frankly surprised, with our efforts this year and the resulting endorsements for PLI reform for 1994. On April 23, 1993, Governor Brereton C. Jones endorsed KMA's proposal for a Constitutional amendment to limit jury awards in malpractice cases. Governor Jones also proposed arbitration and mediation to resolve conflicts in instances of alleged malpractice. KMA is not generally enthusiastic about the arbitration concept unless there is agreement between the parties that mandates it be binding or admissible in the event the decision is appealed. While we will continue to work with the Governor and the General Assembly on other avenues of tort reform, we believe that only by limiting noneconomic damages can we truly slow down the proliferation of awards and the costs of liability insurance and defensive medicine. Endorsement of KMA's proposal was also included in the proposal for health care reform adopted by the Senate Minority (Republicans) during the special session. Other endorsements included a package presented by three minority (Republican) members of the House who proposed a $250,000 limit on noneconomic awards.

In addition to the Governor's personal endorsement of tort reform, the Governor's Task Force, the Governor's Health Care Commission, and the current Legislative Subcommittee on Access to Care have all endorsed tort reform as an important facet in any reform of the health care system. For the first time in history we have the support of powerful political allies needed to bring this issue before the public. Consequently, we are "cautiously optimistic" of our changes to place the Constitutional amendment to limit noneconomic awards on the ballot in 1994. We continue to work closely with major health care providers, allied health groups, insurance companies, along with state and local Chambers of Commerce to achieve our goals. We recognized years ago that this would not be an easy task. We have been disappointed before and may experience additional setbacks in the future. However, it is clear that we must continue this fight, no matter how long it takes to achieve a fair and equitable legal system where all patients and providers are treated fairly and justly.

On the federal level, we continue to work with the American Medical Association and the Kentucky Congressional Delegation in support of national legislation to resolve the liability problem. We continue to support the California reforms which place a $250,000 cap on noneconomic awards. The Clinton proposal for "enterprise liability," which would transfer the liability burden from doctors to the enterprises through which they give care, met wide-scale opposition as part of health care reform. KMA joined with all other states and specialty groups in denouncing this proposal which would have essentially taken the practice of medicine from physicians and given control to facilities.

Ultimately, our success or failure will depend on individual physicians working in their local communities to educate legislators, patients, local media, and the public on the pervasive influence the legal system has on the cost and provision of health care services.

Thank you for the opportunity to serve and my sincere thanks to the members of the Committee who represent you so well on this vital issue.

Wally O. Montgomery, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the Report of the Committee on Professional Liability Insurance and thanks the committee and its Chairman, Wally O. Montgomery, MD for its work and informative report.

Reference Committee No. 3 recommends the Report of the Committee on Professional Liability Insurance be filed.

Report of the Committee on Impaired Physicians

The work of the Committee on Impaired Physicians has expanded considerably this year. The Committee has continued its routine of bimonthly meetings has had ad hoc meetings, as necessary, on a number of occasions. The frequency of the meetings has increased with the added responsibilities the Committee has assumed with regard to monitoring and the increased number of individuals identified as needing the Committee's assistance. The Committee currently has 75 active cases.

The treatment process was finalized and refined during the year. The Committee has developed a document to describe this process and to provide guidelines for use by hospitals and other groups. This document was necessary to provide some direction to those groups and facilities who must deal with impaired physicians day-to-day. Together with the Doctoring Under the Influence program previously constructed by the Committee, this process was felt to be helpful.

The Committee's other major areas of involvement also increased this year. These have included structuring and conducting interventions with impaired individuals, providing and assisting in assessment and evaluation of impairments, identifying and working with acute treatment facilities, the organization and conduct of specific aftercare and extended therapy phases, and advocacy for the recovering individuals.

All of these efforts are enhanced by a continued close working relationship with the Board of Medical Licensure. Many individuals are first identified by the Board, which then withholds final action on licensure pending appropriate recovery efforts through the Impaired Physicians Committee's process.

The Committee also has enjoyed increased and enhanced joint activity with the medical schools. Through the Committee's efforts, some curricula hours at the University of Louisville are devoted to substance abuse and the Committee's work, and this has encompassed inclusion in Grand Rounds efforts. At the University of Kentucky, the Committee has been fortunate in achieving significant support in educational offerings, as well as direct work with impaired physicians in training.

Efforts have continued this year to develop a free-standing foundation for impaired physician activities. The Kentucky Physicians' Health Foundation has been incorporated as a free-standing, tax-exempt organization, and some funds have been solicited from liability carriers for its operation. The Directors of the new Foundation are members of the Board of Medical Licensure, the KMA Board of Trustees, and the Committee. Under the Foundation structure, the Committee's input will remain as a dominant influence because of its reliance on voluntary help directly to impaired individuals across the state. Before the funding is finalized, the Chairman of the Committee has been selected to act as the interim Medical Director.

Until an Internal Revenue designation is completed, funding cannot be received but, as previously mentioned, it has been committed by liability insurors. In the long term, broader funding will be sought from the Board of Medical Licensure. To accomplish this, legislative changes to the medical licensure law will be sought which will allow the Licensure Board to formally contract for impaired physician activities, to allot monies to pay for these contracted services, and to grant immunity to individuals for good faith acts while involved in impaired physician efforts.

Funds were solicited again this year for the Benevolent Fund, which remains under the control of the Board of Trustees. Funds were used this year to assist in deferring treatment costs for two individuals. Two loans previously made from the Fund were repaid.

As alluded to earlier, this entire system would not and could not effectively operate without the strong voluntary support of the Committee members. Not only do they provide help on a one-on-one basis but, collectively, consensus decisions are made which best suit the operation of impaired physician activities and the individuals being treated.

It is also important to note the help and support of many individuals who truly have been their "brother's keeper," and the support of the entire membership of the Board of Trustees is also gratefully acknowledged.

Burns M. Brady, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the Report of the Committee on Impaired Physicians and lauds this committee and its Chairman, Burns M. Brady, MD, for their dedicated, extensive volunteer work with impaired physicians. Reference Committee No. 3 encourages the leadership and membership of KMA to continue supporting and promoting the appropriate utilization of the Committee on Impaired Physicians in our medical communities. It is the desire of Reference Committee No. 3 that each member of the House of Delegates fully understand that the Committee on Impaired Physicians stands ready to assist any facility or community that is experiencing a problem with an apparently impaired physician.

Reference Committee No. 3 recommends the Report of the Committee on Impaired Physicians be filed.

Report of the Committee on Care for the Elderly

The Committee on Care for the Elderly again held a forum this year, as in years past, for the principals in elderly care. The obvious topic for the forum this year was health care reform, and the forum was conducted just after the adjournment of the Special Session of the Kentucky General Assembly. Members of the forum are the Committee members and representatives of the AARP, the Kentucky Association for Older Persons, a representative of the State Government Advisory Committee on Senior Citizens, and the Kentucky Association of Health Care Facilities.

The goal of the forum was to provide an opportunity for each of these representatives to consider health care reform issues together and to exchange ideas. A representative of the Governor's office indicated that efforts were ongoing after the Special Session with all affected groups until the issue can again be addressed by the General Assembly. The focal issues that the Governor was sponsoring were access and cost control; and long-term care, which probably most affects the elderly, figures prominently in those foci. Because of improved lifestyles and better medical care, the aging population will become "younger," and thus will assume an even greater role in health care delivery. The Governor also favors the so-called "gatekeeper" concept, and this appears to have support among elderly groups.

A KMA legislative representative indicated support for the gatekeeper concept and support of the stated views of the Governor's proposal, although financing obviously continues to be the major point of controversy. Some KMA concerns related to the spindown provision for Medicaid eligibility and more focus on home care provided by relatives and dependents.

Nursing home care also looms large as a KMA concern, and it was noted that while nursing home expenditures once represented 40% of the Medicaid budget, they now represent only 17%. A representative of the nursing home association indicated the responsibility of patients to participate financially in their care, but indicated the inequity of being required to expend all assets.

Another major concern in care for the elderly is the need for additional nursing home beds. Commonly, patients have to be institutionalized out of state because of unavailability of beds.

There was general agreement, too, that more attention should be given to advance directives. While the Kentucky law now acknowledges living wills and health care surrogates, many patients have not availed themselves of these documents and the law requires the administration of extraordinary life support measures in the absence of these documents.

General health care efforts for the elderly will suffer in the future as long-term employment becomes more rare and fewer employers offer coverage to employees' dependents, according to one of the representatives of the elderly organizations. More efforts need to be undertaken to increase primary care physicians, and alternative forms of care, such as home health care, are supported by the elderly groups. The elderly groups are also sensitive to the need for additional nursing home beds and support tort reform.

Each of the Committee members contributed concerns of their physician colleagues which included a suggestion for financing based on additional taxation of alcohol and tobacco products, the oftentimes poor management of medical care administratively, a great need for insurance reform, a need for stronger educational emphasis on primary care, and a lack of adequate long-term care insurance.

All agreed that significant health care reform would not occur unless all principals could achieve some consensus on change. Needed change carries a mandate that all affected groups will "suffer," at least in economic ways, but access and cost must be sincerely addressed by everyone.

The Committee was gratified with the forum and plans to continue this very helpful information exchange in the future.

S. Philip Greiver, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the Report of the Committee on Care for the Elderly and thanks the committee and its Chairman, S. Philip Greiver, MD, for their work and report.

Reference Committee No. 3 recommends the Report of the Committee on Care for the Elderly be filed.

Report of the Ad Hoc Committee to Implement 1991 Resolution M (Do Not Resuscitate) Addendum to the Report of Chairman, Board of Trustees

The Ad Hoc Committee to Implement 1991 Resolution M (Do Not Resuscitate) was formed after the adoption of the Resolution by the 1991 Kentucky Medical Association House of Delegates. Resolution M called for the Kentucky Medical Association to:

a) work with representatives of appropriate professional groups and organizations, as well as government and regulatory authorities, if necessary, to develop a uniform, coordinated, and rational approach with respect to the terminally ill patient who does not wish to be resuscitated or to receive extraordinary life-prolonging treatment in the pre-hospital environment;
b) develop a standard prehospital DNR form and to pursue statewide acceptance of this form by means of education;
c) seek the necessary legislative and regulatory changes to protect the patient's right to self-determination, as well as to protect the activities of those health care professionals who follow such directives;
d) work toward development of a statewide, standardized, reasonable method for the immediate identification of patients who have a valid DNR order in effect.

Under the American Heart Association Guidelines for the initiation of cardiopulmonary resuscitation (CPR), used by most EMS systems, all pulseless and nonbreathing patients receive cardiopulmonary resuscitation except those meeting specific criteria for irreversible death. Application of this rule frequently leads to care which may be inappropriate in cases of individuals in the end stages of a terminal illness. Therefore, the EMS provider is often put at odds with families who desire no CPR, but who, in the stress of nearing death of a loved one, called 911. Living Wills and the use of Do Not Resuscitate (DNR) documents in the hospital do not address the problems of the EMS providers outside the hospital setting. Kentucky has no standard DNR protocol, and each hospital develops its own guidelines.

There must be a standardized system of identifying the terminally ill patient in the nonhospital setting which can be recognized by EMS providers statewide. Guidelines need to be developed and made uniform. Current Living Will and Health Care Surrogate Acts should be amended, or new legislation drafted, to allow inclusion of nonhospital DNR orders and to provide immunity for providers. A mechanism for nonhospital validation of a DNR order or Living Will declaration needs to be implemented.

After an in-depth study of legislation adopted in other states and a tremendous amount of material on nonhospital DNR orders, it was the consensus of the Committee to propose legislation that was introduced during the 1992 General Assembly (HB 629), with appropriate Committee changes to reflect the charge of Resolution M. This legislation generally states that all adults possess the fundamental right to control decisions relating to their own medical care, regardless of their location or the type of provider rendering medical assistance, including the decision to have provided, withheld, or withdrawn medical or surgical means or procedures calculated to prolong their lives. This fundamental right also includes the authority to delegate the health care decision to a surrogate. Other relevant portions of this legislation deal with patient declarations (notification and revocation), immunity provisions for health care providers, and surrogate hierarchy. This legislation would not require the patient to submit a written form to make the health care decision effective. The state's current "Kentucky Living Will Act" and "Health Care Surrogate Act" would be repealed by adoption of this proposed legislation.

The Committee's goal is to seek passage of legislation during the 1994 session of the Kentucky General Assembly. With that in mind and because the Committee feels that in order to pass legislation there must be a common ground among interested organizations, a Coalition has been formed by the Committee. The Coalition is made up of a representative from each of the following organizations: KMA's Ad Hoc Committee to Implement Resolution M, CHR's Emergency Medical Services Advisory Committee, Catholic Conference of Kentucky, Jefferson County Medical Society's Emergency Medical Services Committee (Resolution M's origin), Kentucky Association for Older Persons, Kentucky Association of Health Care Facilities, Kentucky Association of Hospices, Kentucky Home Health Association, Kentucky Hospital

Association, and the Kentucky Nurses Association. The Coalition will be reviewing the Ad Hoc Committee's proposal and will try to develop legislation that will accomplish the intended result which can be supported by all the organizations represented. The Committee and Coalition will also consider a proposed system for identification of terminally ill DNR patients.

It is hoped that all organizations represented will be actively involved in seeking passage of the legislation, including testifying before the appropriate committees. It is reiterated, however, that this will not be an easy task considering the 1992 General Assembly's defeat of amendments to existing Living Will and Health Care Surrogate statutes.

As Chair, I am grateful to the Ad Hoc Committee members for the tremendous amount of time and effort they have devoted toward this sensitive issue, reviewing the necessary material, and proposing draft legislation. I also appreciate the interest and time of the Coalition members as we work together toward a common goal of passing good health care decision-making legislation for the people of the Commonwealth.

James R. Bean, MD
Chair

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed the Report of the Chair, Board of Trustees, Report of the Ad Hoc Committee to Implement Resolution M (1991) (Do Not Resuscitate), *only* and thanks the committee and its Chair, James R. Bean, MD, for their hard work on this most sensitive issue. The Reference Committee acknowledges the ongoing complexities the Ad Hoc Committee to Implement Resolution M (1991) must face. Reference Committee No. 3 heard from the Ad Hoc Committee Chair and learned that additional important information has been developed since this report was published. The Reference Committee recommends that the new information be acquired and disseminated to members of the House of Delegates in a timely manner.

Reference Committee No. 3 recommends the Report of the Ad Hoc Committee to Implement Resolution M (1991) be filed and the recommendation of the Reference Committee be adopted.

RESOLUTION C

Physician Assistants
McCracken County Medical Society

WHEREAS, physician assistants (PAs) have a long history as dependent practitioners providing quality patient care with the supervision of licensed physicians; and

WHEREAS, national and state-level proposals for health care reform have recommended that practice privileges for physician assistants be expanded to allow greater reliance on PA services for direct patient care; and

WHEREAS, the American Medical Association and the American Academy of Family Physicians have both recently reaffirmed their support of PA practice as supervised by licensed physicians; and

WHEREAS, the American Academy of Physician Assistants and the Kentucky Academy of Physician Assistants have both recently reaffirmed their commitment to the policy of physician assistant practice with supervision by licensed physicians; now, therefore, be it

RESOLVED, that the Kentucky Medical Association continues to support the joint collaborative practice of physicians and physician assistants in which PAs are supervised by licensed physicians; and be it further

RESOLVED, that the Kentucky Medical Association endorses legislation that allows licensed physicians who are approved to supervise physician assistants the authority to delegate to PAs in their practice the prescribing, dispensing, and ordering of nonscheduled medications in accordance with the discretion and responsible oversight of the supervising physician; the experience, training, and scope of practice of the physician assistant; and the needs of the patients served by the practice.

Recommendations, Reference Committee 3:
Reference Committee No. 3 considered Resolution C, Physician Assistants, submitted by McCracken County Medical Society. Reference Committee No. 3 received input from the Board of Trustees and comments from several physicians during the open discussion of Resolution C. Reference Committee No. 3 recommends the deletion of the works "joint collaborative" in the first "Resolved" which would then read as follows:

RESOLVED, that the Kentucky Medical Association continues to support the *joint collaborative* practice of physicians and physician assistants in which PAs are supervised by licensed physicians; and be it further

Reference Committee No. 3 recommends the adoption of Resolution C as amended.

RESOLUTION I

Nursing Home Regulations
Jefferson County Medical Society

WHEREAS, federal and state regulations are being forced on nursing homes, home health care providers, and health care supply vendors; and

WHEREAS, these regulations greatly impact on physicians' time and professional judgment; and

WHEREAS, there are never provisions for funding physicians for this extra time; and

WHEREAS, primary care bears the brunt of these regulations and primary care organizations are not approached before these regulations are put into effect; and

WHEREAS, these regulations add considerable costs to patients in these care areas; and

WHEREAS, the cost effectiveness of these regulations has not been proven; now, therefore be it

RESOLVED, that the Kentucky Medical Association establish a committee or use an existing committee to evaluate how state and federal nursing home regulations impose adverse impact on physicians' time, professional judgment, and the cost of health care; and be it further

RESOLVED, that the KMA ask the American Medical Association for national input, guidance, and action regarding state and federal nursing home regulations which increase the cost of care and interfere with the physician-patient relationship and the physicians' exercise of professional judgment.

Recommendations, Reference Committee 3:
Reference Committee No. 3 considered Resolution I, Nursing Home Regulations, introduced by Jefferson County Medical Society. After discussion with the author of Resolution I, Reference Committee No. 3 recommends the "Resolveds" be amended by addition to read as follows:

RESOLVED, that the Kentucky Medical Association *gather information and* establish a committee or use an existing committee to evaluate how state and federal *regulations for* nursing homes*, home health care providers, and health care supply vendors* ~~regulations impose~~ adverse*ly* impact on physicians' time, professional judgment, and the cost of health care; and be it further

RESOLVED, that the KMA ask the American Medical Association for national input, guidance, and action regarding state and federal *regulations for* nursing homes ~~regulations~~*, home health care providers, and health care supply vendors* which increase the cost of care and interference with the physician-patient relationship and the physicians' exercise of professional judgment.

Reference Committee No. 3 recommends the adoption of Resolution I as amended.

Resolution I, adopted as amended, reads as follows:

WHEREAS, federal and state regulations are being forced on nursing homes, home health care providers, and health care supply vendors; and

WHEREAS, these regulations greatly impact on physicians' time and professional judgment; and

WHEREAS, there are never provisions for funding physicians for this extra time; and

WHEREAS, primary care bears the brunt of these regulations and primary care organizations are not approached before these regulations are put into effect; and

WHEREAS, these regulations add considerable costs to patients in these care areas; and

WHEREAS, the cost effectiveness of these regulations has not been proven; now, therefore, be it

RESOLVED, that the Kentucky Medical Association gather information and establish a committee or use an existing committee to evaluate how

state and federal regulations for nursing homes, home health care providers, and health care supply vendors adversely impact on physicians' time, professional judgment, and the cost of health care; and be it further

RESOLVED, that the KMA ask the American Medical Association for national input, guidance, and action regarding state and federal regulations for nursing homes, home health care providers, and health care supply vendors, which increase the cost of care and interfere with the physician-patient relationship and the physicians' exercise of professional judgment.

RESOLUTION L

Proposed Nerve Gas Incinerator
Madison County Medical Society

WHEREAS, containers of nerve gas stored at the Bluegrass Army Depot in Madison County are deteriorating; and

WHEREAS, the nerve gas containers must be moved or destroyed, both of which may be hazardous to the health of Kentucky residents; and

WHEREAS, movement of damaged nerve gas containers across county or state lines is politically unfeasible and on-site destruction is the most likely solution; now, therefore, be it

RESOLVED, that KMA encourage the Secretary of the Army to consider alternate means of disposing of the chemical weapons stored at the Bluegrass Army Depot other than by incineration; and be it further

RESOLVED, that in the event an incinerator is built in Madison County to destroy chemical weapons stored at the Bluegrass Army Depot, KMA urges Kentucky's Congressional Delegation to limit use of the incinerator to on-site destruction of nerve gas; and be it further

RESOLVED, that KMA vigorously opposes using Bluegrass Army Depot as a national or regional toxic waste disposal facility; and be it further

RESOLVED, that copies of this Resolution be forwarded to the Secretary of the Army and Kentucky's Congressional Delegation.

Recommendations, Reference Committee 3:
Reference Committee No. 3 considered Resolution L, Proposed Nerve Gas Incinerator, introduced by Madison County Medical Society and received input from G. Irene Minor, MD, author of Resolution L, and Board of Trustees member William H. Mitchell, MD, both members of Madison County Medical Society. With the agreement of Doctors Minor and Mitchell, Reference Committee No. 3 recommends that the Resolution be amended to read nerve "agent" in each instance where nerve "gas" is used and the second "Resolved" be amended by substitution and deletion to read as follows:

RESOLVED, that in the event an incinerator is built in Madison County to destroy chemical weapons stored at the Bluegrass Army Depot, KMA urges Kentucky's Congressional Delegation to limit use of the incinerator to *destruction of currently* on-site ~~*destruction of*~~ nerve ~~*gas*~~ *agent and mustard agent*; and be it further

Reference Committee No. 3 recommends the adoption of Resolution L as amended.

Resolution L, adopted as amended, reads as follows:

WHEREAS, containers of nerve gas stored at the Bluegrass Army Depot in Madison County are deteriorating; and

WHEREAS, the nerve gas containers must be moved or destroyed, both of which may be hazardous to the health of Kentucky residents; and

WHEREAS, movement of damaged nerve gas containers across county or state lines is politically unfeasible and on-site destruction is the most likely solution; now, therefore, be it

RESOLVED, that KMA encourage the Secretary of the Army to consider alternate means of disposing of the chemical weapons stored at the Bluegrass Army Depot other than by incineration; and be it further

RESOLVED, that in the event an incinerator is built in Madison County to destroy chemical weapons stored at the Bluegrass Army Depot, KMA urges Kentucky's Congressional Delegation to limit use of the incinerator to destruction of currently on-site nerve agent and mustard agent; and be it further

RESOLVED, that KMA vigorously opposes using Bluegrass Army Depot as a national or regional toxic waste disposal facility; and be it further

RESOLVED, that copies of this Resolution be forwarded to the Secretary of the Army and Kentucky's Congressional Delegation.

RESOLUTION N

Nursing Home Beds
Pulaski County Medical Society

WHEREAS, it is well known that the supply of extended care beds in the state of Kentucky and specifically Pulaski County is extremely limited; and

WHEREAS, the hospitals are finding increasing difficulty in placement of discharged elderly, debilitated patients in need of nursing home care; and

WHEREAS, it is well known that the populace of the country and the state of Kentucky is increasing in age; and

WHEREAS, there will be a dramatic need for long-term facility beds, especially after the turn of the century; and

WHEREAS, many needy patients are being denied hospital admission because beds are being occupied by nursing home-qualified patients without facilities; now, therefore, be it

RESOLVED, that the Kentucky Medical Association address the issue of the limited supply of extended care beds in Kentucky with full vigor and strongly recommend to the Legislative Committee action to bring about resolution of this problem and to devise a master plan to address this issue in the 1990s; and be it further

RESOLVED, that the Kentucky Medical Association recommend to the Kentucky State Legislature this plan of action to help prevent further crises in the delivery of medical care.

Recommendations, Reference Committee 3:
Reference Committee No. 3 reviewed Resolution N, Nursing Home Beds, introduced by Pulaski County Medical Society.

Reference Committee No. 3 recommends that Resolution N be adopted.

Mr. Speaker, Reference Committee No. 3 recommends the adoption of the Report of Reference Committee No. 3 as a whole.

Mr. Speaker, I wish to thank the members of Reference Committee No. 3 for their participation in the review of these issues. Other members of the Committee are: James R. Bean, MD, Lexington; David A. D. Dao, MD, Elizabethtown; Thomas M. Gadient, MD, Henderson; and Kenneth R. Hauswald, MD, Ashland. Reference Committee No. 3 would also like to express its appreciation to Jeanette Thompson for her assistance in preparing this report.

Respectfully submitted,
REFERENCE COMMITTEE NO. 3
Beverly M. Gaines, MD, Louisville, Chair
James R. Bean, MD, Lexington
David A. D. Dao, MD, Elizabethtown
Thomas M. Gadient, MD, Henderson
Kenneth R. Hauswald, MD, Ashland

Report of the Chair KEMPAC Board of Directors

Thank you Mr Speaker, Fellow Delegates and Guests: It is my privilege to report to you on the activities of the KEMPAC Board and organization for the past year.

Due to the states' redistricting of Congressional Districts, there are now only six Congressional Districts. We now have 16 members on the Board, 2 from each Congressional District and 4 Alliance representatives. The Board now consists of the First Congressional District of Dan Miller, MD, and Harry Carloss, MD; Second Congressional District of Al Joslin, MD, and John Downing, MD; Third Congressional District of Wayne Kotcamp, MD, and William VonderHaar, MD; Fourth Congressional District of Harry Carter, MD, and Kenneth Hauswald, MD; Fifth Congressional District of James Crase, MD, and William Pratt, MD; and the Sixth Congressional District representatives are Irene Minor, MD, and Preston Nunnelley, MD. The KMA Alliance serving on your Board are Faye Neel from Owensboro, Barbara Haas of Fort Thomas, Alberta Gerson from Lexington who replaced Sugar Slabaugh, and another member to be named in December to replace Angie DeWeese.

The KEMPAC Board of Directors met September 28, and elected its new officers for the coming year. Serving you will be William VonderHaar, MD, as Vice Chairman; Irene Minor, MD, as Secretary; Wayne Kotcamp, MD, as Treasurer; Preston Nunnelley, MD, as Assistant Treasurer; and for the next year James Crase, MD, as Chair.

Appointed by the KMA Board of Trustees, KEMPAC supports candidates who share our philosophy and concerns with regard to legislation that affects the Medical profession and *quality patient care*. When our *Views* are made known to a candidate, along with *Financial Support* and *Volunteer Work* during their campaign, it is remembered after they take office.

KEMPAC is constantly building its funds to prepare for the next election cycle. The 1994 elections will be upon us very shortly as well as the convening of the Legislature. It is imperative that we gain all of the backing and support possible from every physician and physician's spouse for 1994.

Our current membership for 1993 is 862. Physician membership continues to be only 18% of the active KMA membership. This percentage desperately needs to grow in order to gain the support we need. The KEMPAC Board of Directors recommends that you reaffirm and include the billing of KEMPAC-AMPAC dues in the statewide billing of 1994 KMA dues, and also include "second reminder" statements of KEMPAC statements with KMA "reminder" statements later in the billing cycle. The KEMPAC Board would also like to recommend that you reaffirm the distribution of a "membership boost" letter signed by each KEMPAC Board of Director prior to the May 1994 primaries.

This is a very crucial time for all of us, and now more than ever we need to join as one.

On behalf of the KEMPAC Board, I want to thank you delegates and the KMA Board of Trustees for your continued support and say that it has been my pleasure to have the opportunity to serve as KEMPAC Chairman.

Thank You.

Samuel Jerry King, MD

A motion was made, seconded, and carried to adopt the report of the Chair, KEMPAC Board of Directors.

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF REFERENCE COMMITTEE NO. 4

David W. Douglas, MD, London, Chair

26. Report of the Committee on Medical Insurance and Prepayment Plans
27. Report of the Committee on Claims and Utilization Review
28. Report of the PRO Advisory Committee
29. Report of the Committee to Investigate Changing Trends in Medicine

Resolution J — Assistants at Surgery
(Jefferson County Medical Society)

Resolution K — Insurance Industry Liaison
(Jefferson County Medical Society)

ITEMS FOR CONSENT

Reference Committee No. 4 reviewed the following items and recommends they be filed, by consent of the House, without discussion:

26. Report of the Committee on Medical Insurance and Prepayment Plans — filed.
27. Report of the Committee on Claims and Utilization Review — filed.
28. Report of the PRO Advisory Committee — filed.

Reference Committee No. 4 would like to express its appreciation to the authors of the reports which have been filed for their time and effort spent in gathering this information.

Mr Speaker, Reference Committee No. 4 recommends adoption of the Consent Calendar as a whole.

Report of the Committee on Medical Insurance and Prepayment Plans

The Medical Insurance and Prepayment Plans Committee met one time this year with the emphasis of the meeting on the KMA-endorsed Blue Cross and Blue Shield plan for the membership.

As reported in the past, the Committee has expended considerable time and effort to make this coverage a useful member benefit at a reasonable price. Last year, Option 2000 coverage was offered and Blue Cross and Blue Shield reported that experience in the Option 2000 plan was better than that in the Comprehensive Major Medical plan and, thus, enjoyed a somewhat lower rate increase at renewal.

However, the Committee was very concerned with the overall combined rate increase for all plans, which was over 22%. After considerable discussion, the Committee recommended that the number of coverage options be reduced to three, one Comprehensive Major Medical plan and two Option 2000 plans, one with a $300/$900 deductible and one with a $500/$1500 deductible.

Efforts are also underway to increase the number of people covered by our plans, which should help spread our risk and stabilize premiums. A coordinated marketing effort is being made by both Blue Cross and Blue Shield career staff and the KMA Insurance Agency and, hopefully, this will result in broadened participation in the plan. The Committee will continue to work toward offering a benefit structure at the lowest possible cost for KMA members.

During our meeting in December, Dr Monnig discussed the areas of major activity in health care reform. He reported that KMA leadership has held over 200 meetings in the pat year regarding health care reform with the Governor, his administration, other health care provider groups, and physicians to address this issue. Governor Jones' proposal called for universal coverage which would add 500,000 currently uninsured individuals, to be financed by "funds currently available in the system" and through a provider tax which would be used to generate matching dollars for the Medicaid Program. The Governor's plan would install a five-member Health Care Authority which would be appointed by the Governor. The Authority would set budgets, monitor spending, and be empowered to set or reduce fees and charges when health care expense exceeded the budget targets. Other components of the plan included development of practice parameters and outcome assessment as well as developing measurements of quality care.

The plan also would provide incentives to redistribute primary care providers. There was the possibility of a super licensure board being developed which could eventually usurp most of the current authority of the Medical Licensure Board.

The plan was based on the so-called managed competition approach which places consumers in a number of large "pools" which would, in turn, contract for medical services with organized groups of providers which would negotiate benefits, payments, and other details. Services would be delivered by HMO-type managed care systems. It also was noted that KMA had some concern as to how such a plan might be implemented in rural areas. Physician payment structures might be changed in reform. Studies of the Medicaid Program done on behalf of the state resulted in a recommendation that Kentucky adopt a relative value scale for physician payment. Another possibility that the state is discussing is a capitated type of payment where the primary care gatekeeper would be responsible for specialist referral and payment on behalf of the patients referred to them. Another approach being discussed with the state is to pay hospitals for services rendered by hospital-based physicians. The hospital would then pay the physician.

As this report is being written in June, most major reform issues remain unresolved. Stubborn unemployment, high Medicaid utilization, and tax income under budget projections make universal coverage unlikely, at least in the near term. Insurance reform was discussed, but not enacted in the Special Session, but will undoubtedly receive significant attention from the legislative task force on reform. The Medical Insurance and Prepayment Plans Committee will watch these developments closely and make recommendations for change, as appropriate, during this process.

I appreciate the active participation of the members of the Committee and their continuing commitment to the Committee's responsibilities.

Donald R. Neel, MD
Chair

Report of the Committee on Claims and Utilization Review

The Claims and Utilization Review Committee has experienced diminished need of its efforts this year, although one meeting was conducted. This related to computerized billing methods, rather than the fee charged.

Fee questions are virtually nonexistent, currently, as managed care plans proliferate and, obviously, dominate medical care delivery. With few exceptions, care falls under the managed care category in some means. In this context, managed care can actually be defined as any process that reimburses for medical services other than sole patient payments.

As society and the Legislature focus more and more on cost containment and health care costs in general, a trend toward a universal payment method has been emerging. Whether this method be based on RBRVS, a fee schedule, or some other method, universality of payments has all but been accomplished. Physicians' fees and payments to physicians are closely intertwined with overall health costs in the public view because such costs are easily identified.

These trends become ever more dominant and are obviously of significant concern to physicians. However, as a profession, we should maintain focus on peer review, the quality of care we provide, and fair reimbursement for those services. For these reasons, the peer review process must remain ready not only to defend the patients we serve, but to defend our profession.

K. Thomas Reichard, MD
Chair

Report of the PRO Advisory Committee

The Advisory Committee on the PRO program has had less activity this year than in previous years due to a diminution in the program's activities. In an October meeting, the Committee reviewed a number of issues with representatives of the Kentucky Medical Review Organization, where it was learned that sanctions against physicians continued to revolve primarily around inadequate information.

At this meeting, the Committee learned that the focus of PRO activities would change, revolving around a new mandated direction indicated by the Health Care Quality Improvement Initiative (HCQII). This aspect of the program will focus on improving care through more information furnished to physicians and hospitals, and sanction efforts will attenuate. The program will accumulate aggregate data and then attempt to develop informational programs based on trends these data indicate.

One area of study will be mortality statistics, for example. Data will be analyzed and supplied to physicians and hospitals, and feedback activity will be solicited of a less controversial nature than sanctions. Small area analysis will also be part of the H&CQII program, which will gather data based on hospital peer groups, to include such dynamics as case mix index, total discharges, and transfer in and out rates. Information will also be gathered on patients by zip code and then grouped to present a single hospital market area. This would allow, among other things, to determine variations in care trends, as far as access to care dynamics.

Under the new PRO scope of work, which is in effect at this time, sanction activities have been significantly modified. Cases that in the past have prompted sanctions will continue to be analyzed, but no sanctions will actually be imposed against physicians, although internal records will be kept.

The PRO program will shift emphasis from general oversight of the prospective payment system for hospitals and inpatient care review to oversight of all medical care settings. This will include a change from process of care to a focus on patient outcome measures; analysis of patterns of care rather than individual case review; and an attempt to improve medical practice rather than a review of provider performance.

As indicated earlier, a comprehensive patient outcome data base will be necessary for these efforts as will further development of practice guidelines, which has already been accomplished through national medical specialty groups.

From a political standpoint, it would seem that physician organizations at all levels have had some influence on changing the direction of PRO efforts. From the perspective of the federal government, there seems to be an acceptance of the fact that sanctionary measures that have been previously used are not cost effective in terms of changing medical practice trends. The new PRO efforts attempt to address medical practice under the new scope of work from the standpoint of data analysis and physicians' education.

The future of the PRO program is unknown. The Committee takes no issue with the PRO program's attempts to affect patient care to achieve improved outcomes. However, the Committee has traditionally felt this could be best accomplished through cooperative and educational efforts rather than sanctionary measures, and the Committee applauds the new PRO directions.

James M. Bowles, MD
Chair

END OF CONSENT CALENDAR ITEMS

Report of the Committee to Investigate Changing Trends in Medicine

Because of the activity in Frankfort on health care reform this past year, the Trends Committee met one time. The charge to the Committee is to study and report on evolving delivery and payment mechanisms; to study and report on demographic trends affecting medical practice; to study and report on ethical questions regarding financial considerations versus quality of life; to investigate trends in cost containment activities; and to determine, to the extent feasible, the role of organized medicine in this changing environment.

Managed Care/Managed Competition

Managed care and managed competition are terms heard frequently today. Managed care refers to systems and techniques used by third-party payors to affect utilization and to control payment for health care services. Managed competition is a term given to a regulated free market approach to health insurance. It calls for individuals to buy health insurance as part of large groups organized by sponsors.

The structure of plans under the managed competition model varies considerably. Employer mandated coverage is common, though not universal. Government sponsors bring the uninsured, and in some cases small employers, into the system. Some proposals call for development of new information systems for assessing outcomes, provider performance, and cost/quality trade-offs.

Most managed competition plans are structured around "integrated systems" in which the administration, delivery, and financing of care are performed or managed by a single entity — or one with incentives to effectively direct patients through such entities. Integrated activities could be performed by insurers, insurer-provider partnerships, or health insurance purchasing cooperatives.

Physicians would be able to contract with whatever type of plan they felt to be most desirable or could form their own. However, it is likely that incentives and penalties would cause a shift in the distribution of coverage from traditional to HMO/PPO-type plans. Government regulations, based on current rhetoric, favor managed care plans.

Plans based on the managed competition model will rely heavily on managed care. Government and insurers are gradually shifting the financial risk of patient care to the provider community and those accepting — or having that risk forced upon them — will turn to managed care to assure dollars are spent as efficiently as possible.

While the concept of managed competition was developed by Enthoven in 1978, its recent acceptance as the health cost panacea has been extraordinary. Almost every state health reform effort embodies some elements of managed competition and it is expected that any national reform will be based on the concept. At the same time, the elements of managed care are becoming increasingly sophisticated and, if not more widely accepted among the physician community, are being more widely used.

The debate over managed care continues but there is some information that indicates that managed care is cost effective and medically efficacious. In a report published in the November 1992 issue of the *Archives of Internal Medicine,* Rapaport, Gehlbach, Lemeshow and Teres conducted an analysis of consecutive intensive care unit admissions at a regional tertiary care teaching hospital. Patients in managed care plans were compared with those covered by traditional insurance with respect to length of stay, hospital charges, charges for specific services, and the use of mechanical ventilation. The analysis controlled for severity of illness, case mix, and mortality. The sample cases examined represented medical care, emergency surgery, and elective surgery.

They found that the managed care group, on average, had shorter stays (both hospital and intensive care), lower charges, and less use of mechanical ventilation than the traditionally insured group. The average differences were 30% to 40%. According to the report, differences were

more pronounced in the patients with the lowest severity of illness.

The California Public Employee's Retirement System announced in February of 1993 that its members' premiums would rise by only 1.5% in 1993. The reason given for such a low increase was that the group demanded cost and performance data from providers in managed care programs and used collective purchasing techniques. However, critics said that the group sacrificed benefits while negotiating for savings and the lower premiums reflect reduced benefits.

Some say the savings from managed care plans such as HMOs and PPOs come from discounts on fees and hospital rates negotiated when the programs begin. Once accomplished, managed care plan costs and rates increase at about the same rate as traditional plans. In 1991, the Health Insurance Association of America, a trade group representing the for-profit insurance industry, surveyed over 3,000 US firms. It found that more than half (54%) of the employees in employer-sponsored health plans are now covered by managed care plans. Premiums in those plans increased 14% in 1991, showing identical increases for conventional, HMO, and preferred provider organization plans. HIAA concluded that despite increasing reliance on managed care, with more than half of covered workers now enrolled in HMOs, PPOs, or point-of-service plans, the cost of coverage continues to climb at the same rate as nonmanaged care plans. It is not clear if managed care costs increased along the lines of conventional insurance or if conventional insurance, reflecting a desire to compete with managed care plans and thereby contractually limiting the provider's ability to raise charges, followed managed care increases.

The AMA Council on Medical Service reported in December 1992, that over the period from 1988 to 1991, the average yearly cost increase was 18% for indemnity plans and 15% for HMOs. The report stated that, while not conclusive, the data suggests that after initial savings are achieved, managed care plans may not exert any greater financial restraint on rates of increase in spending than other financing systems.

A June 1992 report from the Congressional Budget Office reviews available studies and literature regarding the effects of managed care on the use and costs of health services. The report concluded that, "Managed care may also be less effective in controlling health care spending than the evidence from the 1970s and 1980s indicates, even for those organizations that are most tightly controlled. In the past, managed care has succeeded largely in reducing hospital use, but similar drops in the future are now less likely. Between 1980 and 1990, community hospital admissions per 1,000 population dropped nearly 14%. At the same time, the average length of stay per admission declined 5%.

"Hospital use has declined throughout the entire population; while those in HMOs use hospitals less, admissions and length of stay have also fallen among the population that is not enrolled in HMOs." The report continues: "Insofar as managed care's impact on spending is linked with its ability to reduce hospital admissions and length of stay, less hospital use means that HMOs will be able to squeeze less waste out of the health care system in the future. And the management techniques necessary to reduce the use of ambulatory care are relatively undeveloped."

Despite the lack of compelling evidence on managed care as a cost effective approach to medicine, it seems clear that government and the insurance industry are heading toward some form of a managed competition delivery system with an emphasis on managed care.

To discuss that movement, the Trends Committee was pleased to have several local individuals who are very knowledgeable about managed care meet with us and share their views regarding managed care and managed competition.

William Galvagni, Vice President for Corporate Development, and Leslie Robinson-Smith, Manager, Contracting Purchaser Relations, Alliant Health Systems, addressed the issue from the institutional point of view.

Dwight L. Blackburn, MD, a member of our committee and Associate Medical Director, Provider Services, Blue Cross and Blue Shield of Kentucky, discussed the insurer's viewpoint.

Nileen Verbeten, Director, Internal Operations, Lexington Clinic, which recently announced its intent to establish an HMO, gave us the perspective of a large physician group.

Dianne Cornwell, Partner, Arthur Anderson & Company, shared her observations from her extensive involvement with developing managed care plans at the national level.

There was agreement among our guests that we are in the midst of a fundamental change in the delivery and financing of health care, and cost is the single driving force. The influence of providers on health care policy has diminished with the power shifting to business and government.

Payors are developing criteria to allow them to determine which providers are the most cost-efficient and will contract with them to provide services. As a result, the current trends toward group practice will accelerate. New structures will develop between physicians and hospitals. Integrated networks or accountable health plans will contract to deliver care to certain populations and share the financial risk. These plans will develop and use extensive data bases to assure that provider members are practicing in a cost-effective manner and to demonstrate the group's cost-effectiveness. The development and use of practice parameters and outcomes assessment will increase and will become more sophisticated.

Emphasis will be placed on preventive care with an emphasis on keeping people out of the hospital. Hospitals will be seen as cost centers instead of revenue centers. As a result, there could be a significant restructuring of hospitals with some changing their mission and others closing their doors. There will be a need to reorient society's thinking about the traditional role of a hospital. Some hospitals will assume a leadership role in creating these physician/hospital organizations, but their influence in the partnership is likely to diminish over time. Hospitals will provide management and financial services with physicians controlling the care. There will be financial incentives for early intervention because it can help control costs and produce better outcomes.

As stated earlier in this report, discounts on fees haven't proven to be useful in restraining costs overall. Government and insurance companies will seek to transfer the financial risk of caring for insured groups to providers. This shift could be in the form of a capitated payment mechanism or through the implementation of global budgets. Physician/hospital integrated networks will negotiate with government and insurers, with contracts going to those entities that can demonstrate high quality, cost-effective care. To enable networks to negotiate under such a structure, Federal Trade Commission regulations will have to be modified and there is some feeling that Congress might authorize such a change in an overall reform package.

Large traditional carriers may serve as the catalyst for these changes. They already have massive amounts of data on provider performance and pricing. Provider profiling systems can review individual, group, and institutional efficiency. Carriers are more particular about providers accepted into their network. They no longer will accept a provider based on a willingness to contract with a carrier. Today, providers must demonstrate an ability to provide quality care in a cost-effective manner.

No one can be certain what format delivery and financing will take in the future. But clearly, the system is changing. The momentum to change has been building for over twenty years. Some form of a national health insurance seems imminent. National health insurance, which failed in the seventies because it was too expensive, is likely to be put into place today to control that expense.

The Trends Committee will continue to monitor this issue. At the time of our meeting in March, President Clinton had not reported his plan and Governor Jones had not called his Special Session on health care. As this report is being written four months later in June, President Clinton has postponed announcement of his reform plan and Kentucky has seen the appointment of yet another special task force on reform. Hopefully, major revisions in our delivery system will be phased in gradually with thoughtful consideration for the impact change will have on our patients. This country's delivery system evolved to its current structure over many years and may not withstand the trauma of instant reform.

I appreciate the active participation of the members of our Committee and the timely information shared by our guests.

Marjorie R. Fitzgerald, MD
Chair

Recommendations, Reference Committee 4:
Reference Committee No. 4 would like to commend the Committee to Investigate Changing Trends in Medicine for its excellent and thorough address of the issues presented in its report. Reference Committee No. 4 feels that this report, with some minor editing, might be used in one of the KMA publications for general distribution to the members of the KMA. Reference Committee No. 4 recommends that Report No. 29 be filed.

RESOLUTION J

Assistants at Surgery
Jefferson County Medical Society

WHEREAS, patient care and safety often are enhanced and at times are dependent on the presence of an assistant surgeon in the operating room, a decision best determined by an informed practicing surgeon familiar with the patient; and

WHEREAS, there has been a growing tendency among insurance carriers to arbitrarily and unilaterally determine which surgical procedures require an assistant surgeon and which do not; and

WHEREAS, it would appear that some third parties are making such decisions for the purposes of cost containment, and with little or no regard to patient care; and

WHEREAS, the risk inherent in such decisions falls primarily on the patient and the surgeon, not the insurance carrier; and

WHEREAS, the cost and complications of an incomplete surgical result or untoward event would far outweigh the minimal cost of an assistant surgeon to prevent such an occurrence; and

WHEREAS, the American Medical Association encourages specialty societies to develop practice parameters in order to promote the most cost-effective, outcome-based clinical practice, and hundreds of practice parameters are complete or under development at this time; and

WHEREAS, the AMA opposes any effort by Medicare or any other third-party payor to limit payment for medically necessary care, especially in the area of assistants at surgery; and

WHEREAS, the AMA further supports and participates in, as appropriate, the efforts of state and specialty societies to develop guidelines for appropriate use of physicians as assistants at surgery; now, therefore, be it

RESOLVED, that the Kentucky Medical Association, in consultation with appropriate specialty societies and other parties, initiate a formal study of the appropriate use of physicians as assistants at surgery, including the collection of guidelines already developed by medical specialty societies; and be it further

RESOLVED, that the KMA, in its role as a patient advocate, disseminate and aggressively promote the results of its research to its members, to the Health Insurance Association of America (HIAA), to third-party payors in Kentucky, and to the general public.

Recommendations, Reference Committee 4:
Reference Committee No. 4 next reviewed Resolution J, Assistants at Surgery, introduced by the Jefferson County Medical Society. The Committee recommends that the two "Resolveds" be deleted and that the following "Resolveds" be substituted in their place:

RESOLVED, that the KMA Committee on Medical Insurance and Prepayment Plans be asked to collect guidelines on the appropriate use of physicians as assistants at surgery already developed by medical specialty societies, and be it further

RESOLVED, that the Committee on Medical Insurance and Prepayment Plans report the results of its study on the use of physicians as assistants at surgery to the Board of Trustees, and recommend how the information gathered be best utilized.

Reference Committee No. 4 recommends the adoption of Resolution J as amended by deletion and substitution.

Resolution J, adopted as amended, reads as follows:

WHEREAS, patient care and safety often are enhanced and at times are dependent on the presence of an assistant surgeon in the operating room, a decision best determined by an informed practicing surgeon familiar with the patient; and

WHEREAS, there has been a growing tendency among insurance carriers to arbitrarily and unilaterally determine which surgical procedures require an assistant surgeon and which do not; and

WHEREAS, it would appear that some third parties are making such decisions for the purposes of cost containment, and with little or no regard to patient care; and

WHEREAS, the risk inherent in such decisions falls primarily on the patient and the surgeon, not the insurance carrier; and

WHEREAS, the cost and complications of an incomplete surgical result or untoward event would far outweigh the minimal cost of an assistant surgeon to prevent such an occurrence; and

WHEREAS, the American Medical Association encourages specialty societies to develop practice parameters in order to promote the most cost-effective, outcome-based clinical practice, and hundreds of practice parameters are complete or under development at this time; and

WHEREAS, the AMA opposes any effort by Medicare or any other third-party payor to limit payment for medically necessary care, especially in the area of assistants at surgery; and

WHEREAS, the AMA further supports and participates in, as appropriate, the efforts of state and specialty societies to develop guidelines for appropriate use of physicians as assistants at surgery; now, therefore, be it

RESOLVED, that the KMA Committee on Medical Insurance and Prepayment Plans be asked to collect guidelines on the appropriate use of physicians as assistants at surgery already developed by medical specialty societies; and be it further

RESOLVED, that the Committee on Medical Insurance and Prepayment Plans report the results of its study on the use of physicians as assistants at surgery to the Board of Trustees, and recommend how the information gathered be best utilized.

RESOLUTION K

Insurance Industry Liaison
Jefferson County Medical Society

WHEREAS, practicing physicians confront dicta from insurance payors which may be confusing, illogical, or contradictory with accepted standards of clinical practice; and

WHEREAS, a growing number of these procedural rulings negatively affect physicians' ability to care for their patients, and often have no appreciable positive effect on good patient care; and

WHEREAS, physicians receive these de facto regulations from a large and growing number of sources, often without a recognizable or easily determined place to respond, question, or appeal such decisions as seem unreasonable; and

WHEREAS, the insurance industry apparently does not have a statewide organization comparable to the KMA; now, therefore, be it

RESOLVED, that the KMA work with the insurance community to develop an efficient mechanism for communication between the medical profession and the insurance industry at the state level.

Recommendations, Reference Committee 4:
Reference Committee No. 4 reviewed Resolution K, Insurance Industry Liaison, submitted by the Jefferson County Medical Society. Reference Committee No. 4 recommends adoption of Resolution K.

Mr Speaker, Reference Committee No. 4 recommends the adoption of the report of Reference Committee No. 4 as a whole.

I would like to thank the other members of the Committee: Max A. Crocker, MD, Lexington; George R. Schrodt, Jr, MD, Louisville; and Joseph G. Weigel, MD, Somerset. I would also like to thank Debbie Best for her assistance and for a wonderful job for her first time as a Reference Committee secretary.

Respectfully submitted,
REFERENCE COMMITTEE NO. 4
David W. Douglas, MD, London, Chair
Max A. Crocker, MD, Lexington
George R. Schrodt, Jr, MD, Louisville
Joseph G. Weigel, MD, Somerset

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF REFERENCE COMMITTEE NO. 5

William M. Renda, MD, Louisville, Chair

30. Report of the Committee on Maternal and Child Health
31. Report of the Technical Advisory Committee on Physician Services (Title XIX)

32. Report of the Committee on Community and Rural Health
33. Report of the Committee on School Health, Physical Education, and Medical Aspects of Sports
Resolution E — Medical School Training for Recognizing Domestic Violence (KMA Board of Trustees)
Resolution F — Electronic Claims (Young Physicians Steering Committee)

ITEMS FOR CONSENT

Reference Committee No. 5 reviewed the following item and recommends it be filed, by consent of the House, without discussion:

31. Report of the Technical Advisory Committee on Physician Services (Title XIX) — filed

Reference Committee No. 5 would like to express its appreciation to the chair and members of this committee for their time and effort in dealing with the issues discussed in the report.

Mr Speaker, Reference Committee No. 5 recommends adoption of the Consent Calendar as a whole.

Report of the Technical Advisory Committee on Physician Services (Title XIX)

The Technical Advisory Committee on Physician Services (Title XIX), "Physician TAC," is one of 11 provider groups represented on the Advisory Council for Medical Assistance. The Physician TAC meets as needed to discuss and evaluate problems and concerns faced by physicians when dealing with the Kentucky Medical Assistance Program (Medicaid). If the Physician TAC determines that the issues discussed require action, the chairman presents these issues in the form of a written report to the Advisory Council and makes a formal recommendation for action.

Pursuant to a formal opinion from the Cabinet for Human Resources in 1991, all Technical Advisory Committees continue to be subject to the provisions of Kentucky open meetings laws, KRS 61.805-61.850. These laws stipulate that meetings shall be open to the public and shall be scheduled to allow effective public observation and news media coverage.

During the past year, the Physician TAC and KMA worked with Medicaid officials for the authority to nominate physicians to serve on the Drug Formulary Advisory Board (previously functioning as the Formulary Subcommittee) and the Drug Use Advisory Board. Both of these advisory boards are mandated by federal law to serve in an advisory capacity to the Medicaid Program. Administrative orders were issued in December 1992 to formulate these advisory boards, and membership on each board includes four physicians selected from a list of nominees provided by KMA. The Formulary Board shall advise the Department for Medicaid Services on matters relating to the outpatient drug list, drug prior authorization process, coverage status for new drugs and other drug-related matters, and shall make recommendations to the Medicaid Commissioner concerning the composition of outpatient drug lists.

Responsibilities of the DUR Board shall include advising the Department for Medicaid Services on matters relating to drug use therapy, making recommendations to the Medicaid Commissioner on retrospective drug use review standards, developing educational topics on common drug therapy problems and improvement in quality of drug therapy, and establishing standards for identification of suspected fraud and abuse.

In other matters, in its final report to the KMA House of Delegates in 1992, the Committee on Maternal and Child Health made a recommendation which was amended by the House to read in pertinent part as follows: "The Committee on Maternal and Child Health recommends that all high-risk newborns covered by Medicaid be followed by their physicians and their designates to insure PKU testing, infant immunizations, access to the WIC program, preventive care, and repeat pregnancy education. . . ." The KMA Board of Trustees referred this matter to the Physician TAC with a recommendation that it be transmitted to the Medicaid Commissioner. The TAC continues to study this issue and is working with the Committee on Maternal and Child Health to more clearly define and understand the concerns expressed in its recommendation.

Other matters considered by the Physician TAC included proposed Medicaid "screening fees" to emergency room physicians. Questions about who should get the screening fee (hospital or physician) or what the breakdown of fees should be were discussed. It was the consensus of the Physician TAC that an agreement resolving this issue should be negotiated in advance by the independent emergency room physician and the hospital. The Physician TAC also reviewed a complaint received from a physician regarding the HCFA 1500 form and the use of the PIN for Medicare and KMAP's provider number. The physician's concerns were addressed, and he was advised that new HCFA forms and utilization of a universal PIN would eliminate the problems.

The Physician TAC spent a fair amount of time during the past year discussing potential Medicaid funding sources and the effect of proposed health care reform on the Medicaid program. Because of the success of the KenPAC system over the last few years, it was the feeling of the Physician TAC that any proposed health care reform package should give serious study to the KenPAC system.

The Physician TAC will continue its efforts to provide a meaningful forum for Kentucky physicians to present their suggestions and ideas in order to provide the best quality medical services to Kentucky's indigent population.

The Physician TAC wishes to thank Commissioner Miller for her assistance throughout the year and looks forward to another fruitful year of meaningful dialogue.

A. O'tayo Lalude, MD
Chair

END OF CONSENT CALENDAR ITEMS

Report of the Committee on Maternal and Child Health

The Committee on Maternal and Child Health has made extensive efforts to deal with problems relating to obstetrical and pediatric care in Kentucky. During the Association year we met in November, March, and May to discuss various aspects of maternal and child health. Our first priority was to deal with a recommendation made by the Committee during its 1991–92 deliberations. The Committee has grown increasingly concerned with the fate of high-risk newborns and in particular those babies born to the state's poorest and least educated women. These mothers usually have no ongoing physician-patient relationship with obstetricians or family practitioners and are unlikely to have routine access to a pediatrician. In 1992 the Committee recommended the following:

> The Committee on Maternal and Child Health recommends that all high-risk newborns covered by Medicaid be followed by public home health nurses to insure PKU testing, infant immunizations, access to the WIC program, preventive care, and repeat pregnancy education.
>
> The Reference Committee of the 1992 House of Delegates changed the recommendation as follows:
>
> The Committee on Maternal and Child Health recommends that all high-risk newborns covered by Medicaid be followed by ~~public home health nurses~~ *their physicians and their designates* to insure PKU testing, infant immunizations, access to the WIC program, preventive care, and repeat pregnancy education. *The importance of preventive health measures, including immunizations, is recognized for all infants and children in the Commonwealth.*

KMA's Technical Advisory Committee on Physician Services (TAC) was assigned to communicate the KMA House of Delegates position on this matter to the Cabinet for Human Resources (CHR). There were some concerns on behalf of both the TAC and the Committee on Maternal and Child Health regarding the potential liability to physicians that would result if the recommendation was implemented as amended. The TAC posed several questions that needed to be considered before the House of Delegates recommendation was forwarded to CHR. In its efforts to implement the recommendation, the TAC asked the Committee on Maternal and Child Health for clarification on the following:

1. What is the definition of a high-risk newborn?
2. What is the potential for medical liability for failure to follow up?
3. Responsibilities listed in the recommendation are more nutritional, educational-related, etc, than medical. Do these activities require physician services?
4. Should it be the physician's responsibility to follow these patients?
5. Will recommendations as adopted lead to stringent regulations placing responsibility and liability upon physicians and their staff?

It was the consensus of the Committee that any child born to a mother covered by Medicaid is potentially a high-risk infant. It would appear that liability may fall upon either the last or referring physician who treated the mother or child to assure that they received "PKU testing, infant immunizations, access to the WIC program, preventive care, and repeat pregnancy education." In addition, it is not uncommon for government, upon receipt of recommendations from a recognized group, to adopt regulations which closely mirror recommendations received. Therefore, the Committee asks the House of Delegates to reconsider its actions in light of these concerns.

After careful review of both the potential for liability and responsibility the recommendation from the House of Delegates may call for, the Committee recommends that the following be adopted in lieu of the 1992 House of Delegates position:

> Recognizing the importance of preventive health measures, including immunizations, for all infants and children in the Commonwealth, the Committee on Maternal and Child Health recommends that all high-risk newborns eligible for Medicaid be visited by public health nurses to assure metabolic screening, access to a primary care provider, infant immunizations, access to the WIC program where indicated, implementation of application for newborns under Medicaid, and repeat pregnancy education.

The 1992 Committee also recommended that KMA research and study the practicality of a separate Cabinet for Health Services in state government. Various health care reform measures proposed during the Special Session on Health Care directly addressed this question and it would appear that extensive changes will take place in health services if and when reform measures are considered. In the event nothing happens in this area during the special session scheduled for the fall of 1993, or in the regular 1994 session, the Committee will keep this item on its agenda for further consideration.

The Committee continues to promote breast-feeding as the superior method of infant feeding. Committee member Ronald J. Lubbe, MD, discussed the "Second Follow-up Report: The Surgeon General's Workshop on Breastfeeding and Human Lactation" and reported on several recommended activities that promote breast-feeding. Dr Lubbe noted that KMA was cited by Kentucky Best Start for adoption of Resolution T in 1991, which supports education and promotion of breast-feeding during prenatal visits. The Kentucky Best Start Program provided Committee members with informational material regarding its breast-feeding promotions and incentives. In his report, Dr Lubbe noted that the essence of the "Second Follow-up Report" was summarized into ten steps entitled "WHO/UNICEF's Ten Steps to Successful Breast-Feeding." The Committee mailed these steps to Kentucky's hospitals that provide obstetrical care and encouraged those hospitals to implement the ten steps. The mailing also was directed to all OB/GYNs, family physicians, and pediatricians in Kentucky. Results of a hospital survey conducted by the Department of Health Services were included in the mailing. Following are the "WHO/UNICEF's Ten Steps to Successful Breast-Feeding:"

1. Have a written breast-feeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breast-feeding.
4. Help mothers initiate breast-feeding within a half-hour of birth.
5. Show mothers how to breast-feed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless *medically* indicated.
7. Practice rooming-in — allow mothers and infants to remain together — 24 hours a day.
8. Encourage breast-feeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breast-feeding infants.
10. Foster the establishment of breast-feeding support groups and refer mothers to them on discharge from the hospital or clinic.

Pat Nicol, MD, informed the Committee that the Division of Maternal and Child Health had recently learned that the number of physicians who perform obstetrical care in the state has decreased from 211 to 189 in a two-year period (this excludes Jefferson and Fayette Counties). In an attempt to determine as accurately as possible the number of obstetrical providers in Kentucky, Dr Nicol shared with Committee members a list of all hospitals in Kentucky providing obstetrical services. The Committee has been charged with the responsibility of monitoring the availability of obstetrical care in Kentucky. In 1989 the Committee surveyed Kentucky's OB/GYNs and family practitioners. The results of that survey were provided to KMA members and to various groups and entities of government concerned with the availability of maternal and child care.

The Committee completed a follow-up survey of 1,100 family physicians and OB/GYNs in August 1992 and noted that the response rate of 40% was excellent and that the results should be analyzed. The primary policy issue in conducting this survey was as follows:

1. To gather information on the availability of obstetrical services in Kentucky, particularly in rural areas.
2. To determine the reason physicians cease obstetrical practice.
3. To determine effects the cost and availability of professional liability insurance and the tort system have on the availability of obstetrical services.
4. To provide results of this information to the two Kentucky medical schools for use in increasing the number of obstetricians in Kentucky and to encourage family physicians to provide obstetrical services.

These were the major purposes of the survey. However, there were several other questions which sought opinions of physicians, including whether or not they were comfortable working with mid-level practitioners and the general relationship between obstetricians and family practitioners.

On March 11, 1993, the KMA Executive Committee approved the expenditure requested by the Committee to obtain the services of the University of Kentucky Research Center to analyze the results of the survey. Upon completion of the analysis, the Committee agreed to furnish results of the survey to KMA members and medical school scholarship programs to encourage placement of obstetricians in areas where this type of care is lacking. The survey results will be published in the September 1993 *Journal of the Kentucky Medical Association*. The UK Research Center drew the following conclusions:

> A seriously low proportion of physicians are practicing obstetrics in Kentucky among those who are qualified to do so. Less than one-third of the family practitioners and OB/GYN specialists in the state report that they are currently practicing OB. Perhaps as many as 500 physicians in the state, have no apparent intention of resuming their OB practice. Among those who are or might be practicing OB, reform of the current liability regulations is the single most important thing cited that might enable or persuade these doctors to resume or continue their OB practice.
>
> Working relationships between family practitioners and OB specialists are reported to be quite good throughout the state. Most respondents report their relationships as characterized by consults, referrals, assistance on procedures, or merely "good" relations. There does appear to be some reluctance to only providing partial prenatal care with the intention of transferring the patient before full term, though a significantly higher proportion of physicians practicing OB would be willing to accept a referral under such conditions. Also, two-thirds of the physicians practicing OB indicate a willingness to work with a midwife or a nurse practitioner.
>
> Assuming that an increase in the number of trained health care professionals practicing obstetrics in Kentucky is the desired outcome, it is quite clear from these results that serious reforms in liability regulations are needed in order to encourage OB-trained physicians back into OB practices. Other issues such as increased personnel or higher wages are much less salient in the minds of the respondents. There does not appear to be too much of a need to focus on enhancing the working relationship between family practitioners and OB/GYN specialists, although monitoring of these alliances would clearly be prudent in any case. And since OB practitioners have such a high level of willingness to work with midwives and nurse practitioners, the Committee may wish to consider developing an educational promotion for understanding the role, training, and qualifications of midwives and nurse practitioners.

The Committee has been extremely busy this year, and I want to especially thank those members of the Committee who have been active and whose contributions were extraordinary.

J. Gregory Cooper, MD
Chair

RECOMMENDATIONS:

1. Recognizing the importance of preventive health for all infants and children in the Commonwealth, the Committee on Maternal and Child Health recommends that all high-risk newborns eligible for Medicaid be visited by public health nurses to assure metabolic screening, access to a primary care provider, infant immunizations, access to the WIC program where indicated, implementation of application for newborn under Medicaid, and repeat pregnancy education.

Recommendations, Reference Committee 5:

Reference Committee No. 5 reviewed the Report of the Committee on Maternal and Child Health and its Recommendation No. 1. There was considerable discussion concerning the Recommendation, and the Reference Committee appreciated the testimony provided by the following: Committee Chair J. Gregory Cooper, MD; Committee members Doane Fischer, MD, and Patricia Nicol, MD, who is also Director of CHR's Division of Maternal and Child Health; and KMA Trustee Ronald E. Waldridge, MD.

The Reference Committee would like to thank the members of the Committee on Maternal and Child Health for their devoted efforts on behalf of the families of the Commonwealth.

Mr Speaker, Reference Committee No. 5 recommends the Report of the Committee on Maternal and Child Health and its Recommendation No. 1 be adopted.

Report of the Committee on Community and Rural Health

The Community and Rural Health Committee met on three occasions this year and the major topic of discussion was development of the policy on prevention of the spread of HIV and HBV from physicians to patients during the performance of significant risk procedures. The development of the policy was prompted by a federal requirement for each state to implement the Centers for Disease Control recommendations for preventing the spread of HIV/HBV during significant risk procedures. In 1991, the CDC promulgated a series of six recommendations designed to further reduce the possibility that a health care worker could infect a patient during the course of clinical practice. Those recommendations were: that health care workers should adhere to universal precautions; that there was no basis for restricting the practice of health care workers infected with HIV/HBV who were not performing significant risk procedures; that medical, dental, and surgical organizations should identify significant risk procedures; that health care workers who perform those procedures should know their HIV antibody status; that health care workers who are infected should not perform significant risk procedures unless they sought counsel from an expert review panel; and finally that there was no need for mandatory testing of health care workers.

Four months after the promulgation of these recommendations, Congress passed Public Law 102-141, sponsored by Senator Jesse Helms (R), North Carolina, which specified that each state public health official ensure that the CDC recommendations be followed and include a process for determining what disciplinary or other actions should be taken to comply with federal law. Each state was mandated to comply with the CDC recommendations which had previously been voluntary. States were given a year to adopt CDC guidelines, develop their own guidelines, or request an extension. Failure to comply could result in loss of public health money to states.

In an effort to develop effective regulations that would comply with CDC guidelines, Kentucky requested and was granted an extension to meet the federal guidelines.

Rice C. Leach, MD, Commissioner, Department for Health Services, and Reginald Finger, MD, Director, Division of Epidemiology, requested KMA's assistance in development of a policy for physicians in Kentucky. At its September 1992 meeting, the KMA Board of Trustees empowered the Community and Rural Health Committee to work with Drs Leach and Finger in development of a policy that could be used as a model for development of regulations by the medical, dental, nursing, and podiatry boards of licensure.

After two meetings, the Committee finalized a policy that maintained existing KMA policy regarding voluntary testing for physicians and established a panel that will have the ability to counsel a physician and determine whether the physician should continue practicing. The Committee approved the following policy on HIV/HBV and physicians:

I. Any physician who performs patient care procedures that pose a significant risk of transmission of HIV/HBV to patients should determine his/her HIV/HBV serostatus at intervals, the frequency of which will vary according to the individual circumstances.

II. Any HIV and/or HBV positive* physician should disclose his/her serostatus to the Kentucky Board of Medical Licensure.
 a. A representative of the Kentucky Board of Medical Licensure will convene a review panel consisting of the HIV/HBV positive physician's primary care physician, a clinical infectious disease specialist not involved in the care of the patient, and an epidemiologist representing the Kentucky Department for Health Services. A professional peer with similar medical practice will also be included. Other physicians may be added as appropriate.
 b. The review panel should be responsible for monitoring the HIV/HBV positive physician's adherence to universal precautions and monitoring his/her clinical competency. The panel should be responsible for recommending practice restrictions if indicated. Those physicians who do not report to the Board as required above or do not abide by the review panel may be subject to disciplinary action by the Board. The review panel should be empowered to monitor the HIV/HBV positive physician for compliance with any practice limitations established by the panel to monitor compliance with universal precautions, and to evaluate the effects of the disease on the physician's competency.

III. The KMA encourages and promotes infection control training among all physicians including the elements of universal precautions. All physicians should at all times adhere to universal precautions.

IV. A mechanism should be devised by the KMA or other agencies whereby HIV/HBV positive physicians may receive adequate counseling, career modification advice, and other assistance as developed by a physician advocacy committee.

*HIV defined, as positive, by a positive western blot or its equivalent, in accordance with CDC Guidelines.
HBV positivity defined as significant if associated with an e antigen positive as performed by an FDA approved laboratory.

The Committee considered other issues as well. Resolution F, School Health Clinics, was sent to the Community and Rural Health Committee by Reference Committee No. 5 of the 1992 KMA House of Delegates, and calls for the Kentucky Medical Association to seek administrative and legislative commitment to amend the Kentucky Education Reform Act (KERA) to require schools (grades K-12) to include health education in the curriculum. KERA allows each school district to make the decision on the type of health education to be taught in the respective school district. Various health care reform proposals introduced in the special legislative session on health care reform contained provisions for health education in the schools. The KMA supported many of those specific proposals for health education. In consideration of Resolution F, the Committee recognized its merit but delayed action for further study to see what proposals are developed through health care reform initiatives at the state level. The Committee also recommended that Rice C. Leach, MD, and the Department for Health Services look into the issue. The Committee will consider the issue at subsequent meetings.

The "Blue Ribbon" Subcommittee on Domestic/Interpersonal Violence, chaired by Baretta R. Casey, MD, met on February 17, 1993, and finalized proposals for an educational packet for physicians and patients. The Subcommittee was charged with recommending to the Kentucky Medical Association methods to improve physician education in order to better deal with the complex problem of domestic/interpersonal violence. The educational packet developed by the Subcommittee will consist of a state map with locations and phone numbers of all spouse abuse centers in the state, a child abuse brochure, an adult/elderly abuse brochure, and a separate patient brochure. The packet will be mailed to every active physician in the state in August 1993 before the KMA Annual Meeting. The packets will also be mailed to all county medical societies in the state so that they can help educate their communities on domestic violence. From Reference Committee No. 5 of the 1992 KMA House of Delegates, Resolution S, Family Violence, encouraged the Kentucky Medical Association to develop an educational packet on domestic/interpersonal violence to send to county medical societies.

The Subcommittee also developed a Resolution on Medical School Training for Recognizing Domestic Violence which will be submitted from

the Board of Trustees to the 1993 House of Delegates. The Resolution encourages the state medical schools to implement training courses on recognizing and treating domestic violence in patients into the medical school curriculum. Through its current activities, the Subcommittee is achieving the short- and long-term goals that it set for itself at its initial meeting which were:

Short-Term

— Educate physicians on the problem of domestic violence.
— Instruct physicians on the present laws in Kentucky as they relate to reporting known and suspected domestic violence.
— Educate communities by providing brochures to physician offices, hospitals, and other public places.

Long-Term

— Recommended that medical schools in Kentucky implement courses on diagnosing abused victims.

In addition, through the work of the Subcommittee, Dr Casey was instrumental in getting four KMA physicians appointed to the Attorney General's Task Force on Domestic Violence, which will strengthen the medical community's input into any recommendations that come forth from the Task Force.

Finally, Reginald Finger, MD, reported to the Committee on the involvement of the Division of Epidemiology in health care in Kentucky. Dr Finger's department is divided into three sections and has made significant progress in improving the delivery of public health in communities throughout the Commonwealth.

We thank the KMA Board of Trustees for being permitted to serve and urge members to refer relevant concerns to the Committee.

Ardis D. Hoven, MD
Chair

Recommendations, Reference Committee 5:
Reference Committee No. 5 reviewed the Report of the Committee on Community and Rural Health, and a member of that Committee, Beretta Casey, MD, provided expanded information on its activities. Particular mention was made of domestic expanded information on its activities. Particular mention was made of domestic violence and the development of a federally required policy to implement a CDC recommendation on the prevention and spread of HIV and HBV from physicians to patients during the performance of significant risk procedures. Additional information was provided by Scott Scutchfield, MD, and Edward Scofield, MD. The Reference Committee would like to commend the Community and Rural Health Committee for its dedicated work.

Mr Speaker, during discussion it was pointed out that one of the medical schools requires that any student who tests HIV positive be dismissed with no thought given to career modification or financial burden. Reference Committee No. 5, therefore, recommends that KMA secure information from Kentucky's medical schools as to their policies regarding HIV positive students, their subsequent dismissal, and what opportunities are available for counseling, career modification advice, and other assistance, and that this information be referred to the appropriate committee for review and possible recommendation.

Mr Speaker, Reference Committee No. 5 recommends the Report of the Committee on Community and Rural Health be filed and the recommendation of the Reference Committee be adopted.

Donald R. Kmetz, MD, Dean of the University of Louisville School of Medicine, noted that apparently the Reference Committee had received misinformation, and he stated that the University of Louisville does not have a policy of dismissing HIV positive students. Dr Kmetz noted that he had given copies of U of L's policy on this subject to the Board of Trustees. The Speaker noted that the Dean of the University of Kentucky had related that he did not believe UK dismissed HIV positive students.

Report of the Committee on School Health, Physical Education, and Medical Aspects of Sports

The Committee on School Health, Physical Education, and Medical Aspects of Sports met on three occasions in the 1992–93 Associational year. One Resolution from the 1992 KMA House of Delegates was referred to the Committee from the KMA Board of Trustees for study and action. The Resolved portion of Resolution N, Education and Students on the Hazards of Ultraviolet Radiation (Tanning Beds), stated: "Resolved, that the Kentucky Medical Association work with the Kentucky State Board of Education to include in the curriculum appropriate information for teachers to educate their students about the hazards of ultraviolet radiation and tanning parlors." The Committee agreed that information should be gathered on the hazards of these devices so that appropriate recommendations could be made to the State Board of Education. It was noted that the Kentucky Education Reform Act (KERA) prohibits mandates to education curriculum; however, the Governor's Health Care Reform Proposal recommended that health education be required in grades K-12.

The Committee forwarded Resolution N and supporting materials to the State Board of Education for consideration. Betty Edwards, EdD, Director, Division of Curriculum, responded to KMA's concerns. Dr Edwards noted that Thomas C. Boysen, PhD, Commissioner of Education, had referred the letter regarding Resolution N to her office for response and stated:

> The KMA House of Delegates is to be commended for its interest in students and its desire to include the hazards of ultraviolet radiation and tanning parlors into the curriculum. The passage of the Kentucky Education Reform Act (KERA) changed the roles and responsibilities of the Kentucky Department and the State Board for Elementary and Secondary Education in terms of curriculum. Now, local school districts and schools have the unique opportunity to determine curriculum and those policies which govern its development and implementation. However, they are accountable for their students to achieve the six learning goals and 75 learner outcomes established by the state. One of those outcomes reads, "Students demonstrate skills and self-responsibility in understanding, achieving, and maintaining physical wellness." A curriculum framework has been developed by the Department of Education and will be disseminated in June to all school districts and public schools. The framework will provide direction to local curriculum writers as they develop curriculum. In the framework, each outcome has been further defined by demonstrators which may specifically address the issues in your Resolution as follows:
>
> • Evaluate and select actions which can enhance growth, development, and wellness (elementary level).
> • Select behaviors and make lifestyle choices to prevent or minimize the risk of disease (middle school level).
> • Analyze impact of personal behavior on body systems (high school level).
> • Apply wellness concepts to health maintenance (high school level).
>
> While the Committee will continue the dialogue with the Department of Education, the indication we have is that any impact upon a school's curriculum will only come through the local Board of Education and the schools themselves.

In 1991 the KMA House of Delegates adopted Resolution Q which directed that KMA take action to encourage uniform health education and physical fitness proficiency testing in all schools. Terry Vance, a Department of Education staff person and an ex-officio member of this Committee, reported that she had referred Resolution Q to her department but had met with opposition due to the limitations of the Kentucky Education Reform Act of 1990. Ms Vance was in hopes that during the 1993 Special Session on Health Care Reform the issue of health education and physical fitness would be addressed. Due to the limitations of the Kentucky Education Reform Act of 1990 (KERA), it is recommended by the Committee that county medical societies be made aware of Resolution N (1992), Education of Students on the Hazards of Ultraviolet Radiation (Tanning Beds), and Resolution Q (1991), Health Education and Physical Fitness Testing in Kentucky Schools, and that they be urged to participate in the development of curriculum on local Boards of Education and in local school systems and to encourage an appropriate health and safety curriculum.

In 1990 the Kentucky General Assembly adopted House Bill 443, legislation which prohibited rules or regulations that would restrict pupils in grades 7-8 from participating in high school sports. This Committee and KMA registered objection to this legislation which would permit 12- to 13-year-old boys to participate in varsity contact sports, particularly football, wrestling, and soccer. During the 1992 General Assembly, KMA worked with Representative Jody Richards (D), Bowling Green, to introduce House Bill 750 which restricted high school varsity wrestling, soccer, and football to students who have successfully completed the eighth grade. Even though HB 750 became

law July 1, 1992, the Kentucky High School Athletic Association (KHSAA) has been reluctant to adopt regulations enforcing the law.

As Chair, I presented testimony on KMA's behalf to the Kentucky State Board for Elementary and Secondary Education (SBESE). Terry Vance of the Department of Education accompanied me at this meeting. This Committee's request that SBESE direct KHSAA to adopt a bylaw regarding implementation of HB 750 was adopted. Julian Tackett, a member of KHSAA staff and an ex-officio member of this Committee, assured KMA that KHSAA would follow the directions of SBESE and draft appropriate regulations to become effective for the 1993–94 school year. However, at the next meeting of the Committee, Mr Tackett reported that after much discussion between KHSAA and the Department of Education regarding the implementation of HB 750, the Department had asked KHSAA to survey high schools to determine the number of students allowed to participate in varsity sports prior to successfully completing the 8th grade. Upon completion of the survey, the Department will take action on the implementation date of HB 750.

It was reported that current plans called for implementing the regulations effective with the 1994–95 school year. Mr Tackett requested that I and another representative of the Committee, Mary L. Ireland, MD, along with himself and a KHSAA Board member and KMA staff member, meet to discuss this legislation prior to the finalization of the effective date. Dr Ireland and I met with KHSAA officials on April 8, 1993, regarding the implementation of HB 750. We hope this brings to an end a controversy that has existed for the past four years.

In 1989 the Committee developed a 64-page "Syllabus of Sports Injury Care for the Kentucky High School Coach." The original syllabus was a collaborative effort of KMA with a grant from the Department of Education. We originally printed 3,500 copies but in just four years we are completely out of the books. With the approval of the KMA Board of Trustees, the Committee decided to undertake a fund-raising project. Upjohn Pharmaceutical Company agreed to underwrite the printing costs of additional syllabuses if Committee members would sponsor marketing panels across Kentucky. Upjohn contributed $100 to the syllabus fund for each attending physician. Panels were held in Lexington, Louisville, Ashland, Crestview Hills, and Danville. We are pleased to report that we reached our goals of $6,000 and will begin printing the second edition of the syllabus. Special thanks is given to Mrs Susan McClellan of the Upjohn Company who graciously agreed to support the proposal and who handled the required administrative duties.

The Committee was made aware this year that some coaches around the state have been requesting a KHSAA rule change regarding the starting date of football practice with pads. KHSAA Bylaw 25, which KMA worked with the Department of Education to develop, now states that organized practice in pads should not begin prior to August 1. Requests have been received to amend the bylaw to allow practice "30 days before the first scheduled contest." The Committee reaffirmed its position that the current bylaw is in the best interest and safety of Kentucky's school children and that a change could create a situation where football practice with pads might be held in mid- to early July, thereby creating a health hazard to student athletes. Team physicians are urged to discuss with their high school coaches the risk this situation could incur to players. A letter was written to Commissioner Billy Wise outlining the Committee's concerns and reaffirming support of existing policy.

In response to a 1992 request from Fayette County Medical Society, Committee members W. Ben Kibler, MD, and Michael J. Miller, MD, researched current policies regarding protective equipment in Kentucky high school athletics. Their recommendations regarding current policies were compiled and distributed to the Committee for consideration. These recommendations will be inserted in the second printing of the syllabus and copies will be distributed at future symposia. The possibility of including the importance of protective equipment on future sports medicine symposia agendas is being considered.

Julian Tackett, KHSAA, requested that the Committee review a proposed experimental rule for football regarding protective casts worn by players to protect an injury. The proposed rule would require a physician's written order for a cast to be worn during play. Rules of the National Federation of State High School Associations currently permit game officials the authority to allow or disallow protective casts, appliances, etc, during play. The Committee discussed the dangers of the equipment to other players. Committee member James M. Bowles, MD, will work with Mr Tackett regarding current policy and will attempt to make a determination as to how decisions will be made regarding football players wearing protective casts during play. Mr Tackett also presented to the Committee a brochure designed and printed by KHSAA for use by high school administrators, coaches, and officials regarding communicable disease prevention and precaution. KHSAA requested the endorsement of the Committee and the brochure was referred to the KMA Executive Committee for approval. KMA Executive Committee approval was received in February.

Almost 1,300 coaches, including cheerleader instructors, attended the 12 regional sports medicine symposia sponsored in 1992 by the Kentucky Medical Association. Coaches are required by the State Board of Education to attend a symposium every two years. Several considerations were made due to complaints on the length of the meetings and costs. The Committee established registration fees of $20 for pre-registration and $30 for late registration and walk-ins. Some coaches have complained about the length of the seminar (seven hours). The possibility of a shorter day was discussed; however, it was felt that a seven-hour symposium day was justified and would remain mandatory.

Symposia chairs were requested to avoid complicated medical topics such as MRI and encouraged to address issues more related to daily activities of coaches and players. Ample time for cheerleader coach topics was also encouraged. It was noted that cheerleaders practice 3-4 hours a day or more when preparing for competition and coaches should be cautioned not to overwork young athletes. Chairs were also encouraged to include the importance of pre-participation examinations as a future topic for symposia and to stress that student athletes be seen by their primary care physician prior to participation. The Committee will discuss the possibility of limiting the number of pre-participation exams performed at local high schools in the future to students with special needs.

The following dates, locations, and sponsors were established for the 1993 Sports Medicine Symposia for Kentucky high school coaches:

1. April 23, 1993, Ramada Inn, Maysville
 (Meadowview Regional Hospital & Charlotte Harris, MD, Sponsors)
2. May 6, 1993, Gheens Academy of Male High School, Louisville
 (Ray Shea, MD, and John Ellis, MD, Co-sponsors)
3. May 8, 1993, Bethlehem Academy, Elizabethtown
 (E-town Surgical Center & William C. Nash, MD, Sponsors)
4. June 11, 1993, Murray State University, Murray
 (Murray-Calloway County Hospital & John Yezerski, MD, Sponsors)
5. June 18, 1993, Madisonville Community College, Madisonville
 (James Bowles, MD, & Joseph Roe, MD, Co-sponsors)
6. June 19, 1993, Union College, Barbourville
 (Ben Kibler, MD, Sponsor)
7. June 19, 1993, Kings' Daughters Hospital, Ashland
 (Garner Robinson, MD, Sponsor)
8. June 19, 1993, Holiday Inn North, Lexington
 (David N. Caborn, MD, Sponsor)
9. July 16, 1993, Northern Kentucky University, Highland Heights
 (Michael J. Miller, MD, Sponsor)
10. July 30, 1993, EKU, Richmond (In Conjunction with KAPOS)
 (Mary L. Ireland, MD, Sponsor)
11. September 11, 1993, EKU, Richmond (Make-up Symposium)
 (Mary L. Ireland, MD, Sponsor)

As KMA members can readily see by this extensive report, members work very hard during the year to protect the health and well being of our children and student athletes. I am extremely pleased to work with an outstanding group of physicians who bring great credit to the profession and KMA. They genuinely care for our children and sacrifice a great deal of their time demonstrating total concern. In addition, the Committee thanks all the team physicians who serve as extensions of the Committee and perform an outstanding public service to their community and this Association.

R. Quin Bailey, MD
Chair

RECOMMENDATIONS:

1. Due to the limitations of the Kentucky Education Reform Act of 1990 (KERA), the Committee on School Health, Physical Education, and Medical Aspects of Sports recommends that county medical societies be made

aware of Resolution N (1992), Education of Students on the Hazards of Ultraviolet Radiation (Tanning Beds), and Resolution Q (1991), Health Education and Physical Fitness Testing in Kentucky Schools, and that they be urged to participate in the development of a curriculum on local Boards of Education and local school systems to encourage an appropriate health and safety curriculum.

Recommendations, Reference Committee 5:
Reference Committee No. 5 reviewed the Report of the Committee on School Health, Physical Education, and Medical Aspects of Sports along with its Recommendation No. 1. Committee member Ronald Waldridge, MD, provided additional information concerning the Recommendation.

The Reference Committee wishes to express appreciation to the members of this Committee for their dedication to the students and athletes of Kentucky.

Mr Speaker, Reference Committee No. 5 recommends the adoption of the Report of the Committee on School Health, Physical Education, and Medical Aspects of Sports and its Recommendation No. 1.

RESOLUTION E

Medical School Training for Recognizing Domestic Violence
Board of Trustees

WHEREAS, clinical studies underscore the prevalence of domestic violence and its relationship to continued or repeated trauma and consequent medical and psychiatric problems; and

WHEREAS, more than half of all nonfatal assaults result in injury, and 10% of the victims require hospitalization or emergency medical treatment; and

WHEREAS, a medical encounter may provide the only opportunity to stop the cycle of violence before more serious injuries occur; and

WHEREAS, most physicians will encounter cases of domestic abuse in their practices and must be aware of their obligations in these cases, as well as their potential liability for failing to diagnose and/or report domestic violence; now therefore be it

RESOLVED, that KMA urge Kentucky's medical schools to adapt their curriculum to include training for domestic violence cases including recognizing and reporting abuse, proper techniques for interviewing and diagnosing patients, and proper documentation of abuse of the patient.

Recommendations, Reference Committee 5:

Resolution E — Medical School Training for Recognizing Domestic Violence (KMA Board of Trustees)
Reference Committee No. 5 next reviewed Resolution E, Medical School Training for Recognizing Domestic Violence, introduced by the KMA Board of Trustees, and heard discussion by several members.

Reference Committee No. 5 recommends the adoption of Resolution E.

RESOLUTION F

Electronic Claims
Young Physicians Steering Committee

WHEREAS, insurance carriers are adopting policies of delayed payment for claims submitted on paper and timely payment for claims submitted electronically; and

WHEREAS, computerization can be a costly expense for young physicians entering practice at a time when they have other educational and start-up practice debts; and

WHEREAS, payment delays impact the cash flow of a newly established practice, particularly in underserved and rural areas with large populations of governmentally insured patients; and

WHEREAS, the benefits of electronic claims accrue more to the insurance carrier than to the individual practice; and

WHEREAS, it is inappropriate to penalize physicians who choose not to submit claims electronically; now, therefore, be it

RESOLVED, that insurance carriers which require claims submitted electronically should be encouraged to provide appropriate assistance to help physicians convert to an electronic system in an economical fashion; and be it further

RESOLVED, that until appropriate and economical conversion to electronic claims can be completed, carriers be encouraged to process nonelectronic claims routinely without unnecessary delay.

Recommendations, Reference Committee 5:

Resolution F — Electronic Claims (Young Physicians Steering Committee)
Reference Committee No. 5 reviewed Resolution F, Electronic Claims, introduced by the Young Physicians Steering Committee, and heard discussion concerning this Resolution.

Reference Committee No. 5 recommends that Resolution F be adopted.

Mr Speaker, Reference Committee No. 5 recommends the adoption of the report of Reference Committee No. 5 as a whole.

Mr Speaker, I would like to thank the other members of this Committee, Jack C. Blackstone, Jr, MD, Owensboro; Mark Cannon, Lexington; Stephanie R. Hatfield, MD, Paducah; and John M. Patterson, MD, Frankfort, for their time and thoughtful consideration of the issues referred to the Reference Committee. The Chair would also like to thank Doris Crume for her assistance in the preparation of this report.

Respectfully submitted,
REFERENCE COMMITTEE NO. 5
William M, Renda, MD, Louisville, Chair
Jack C. Blackstone, Jr, MD, Owensboro
Mark Cannon, Lexington
Stephanie R. Hatfield, MD, Paducah
John M. Patterson, MD, Frankfort

Editorial Note: Unless otherwise indicated, the Reference Committee recommendation on each Report and Resolution was accepted. Any opposing or additional action taken by the House is printed in discussion following the item.

REPORT OF REFERENCE COMMITTEE NO. 6

John D. Noonan, MD, Paducah, Chair

34. Report of the Judicial Council
35. Report of the Rural Kentucky Medical Scholarship Fund
36. Report of the Physician-Attorney Liaison Committee
37. Report of the Membership Committee
38. Report of the Young Physicians Steering Committee
39. Report of the Medical Student Section
40. Report of the Resident Physicians Section
41. Report of the EMCK Foundation

Resolution H — Publicity Campaign
(Boyle County Medical Society)

ITEMS FOR CONSENT
Reference Committee No. 6 reviewed the following items and recommends they be filed, by consent of the House, without discussion:

34. Report of the Judicial Council — filed
35. Report of the Rural Kentucky Medical Scholarship Fund — filed
36. Report of the Physician-Attorney Liaison Committee — filed
38. Report of the Young Physicians Steering Committee — filed
39. Report of the Medical Student Section — filed
40. Report of the Resident Physicians Section — filed
41. Report of the EMCK Foundation — filed

Mr Speaker, Reference Committee No. 6 recommends adoption of the Consent Calendar as a whole.

Report of the Judicial Council

The Judicial Council has held two formal meetings this year and has dealt with other issues informally through telephone calls and correspondence.

Of ongoing concern has been the issue of self-referral, which has occupied a good deal of attention at the state, as well as national, level. The position of the American Medical Association, which was considered at three separate AMA meetings, generally holds against passive investment and self-referral done purely for profit. The AMA position was based on the conviction that physicians are not simply business people with high

standards, but individuals engaged in a special calling of healing and, as such, must be patient advocates. The opinion allows self-referral if there is a demonstrated need in the community for the facility and alternative financing is not available, or when the facility is a direct extension of the physician's practice with the physician providing or supervising the services rendered.

A number of proposed and pending pieces of national legislation seek to further restrict physician referral, and it is likely that a referral will be an ongoing matter of discussion for the Kentucky General Assembly. The Judicial Council and the AMA's Council on Ethical and Judicial Affairs will continue to monitor the situation with a view toward modification, if necessary.

Another issue with ethical implications considered by the Council was guidelines for medical consultants. The KMA House had asked the Council to consider mandating some guidelines. The Council considered that such information might most appropriately be developed by the Board of Medical Licensure in order to have any practical effect.

The Council reviewed aspects of guidelines adopted by other organizations, including the AMA, the American College of Obstetrics and Gynecology, and the American Academy of Pediatrics. These guidelines included such requirements as: the expert be licensed to practice in the state in which testimony was to be given; the expert be trained in the same specialty; and that any out-of-state expert be familiar with standards of practice in the state where testimony was given. Currently, the decision as to an expert witness's qualifications is left to the discretion of the trial judge, and the acknowledgment of local standards would likely be brought about during the trial process. The issue of contingency fees to be paid to expert witnesses was also considered and issues concerning rules of evidence were addressed. On review of this information, the Council felt that further consideration should be given to developing guidelines, which are still being reviewed.

A good bit of the Council's activities this year were directed, again, to dealing with patient complaints and acting as arbiter on physician activities. A continuing and disturbing trend has been the high volume of complaints relating to transfer of patient records. In many instances, there has been a refusal on the part of the physician to transfer records to another physician for a variety of reasons, which have included outstanding patient bills.

The Council would like to reiterate its standing policy, previously adopted by the House, that it is unethical for a physician to withhold the release of records due to an outstanding bill. While the original medical records are the physical property of the physician, a physician does not "own" the information contained. Patients should generally be furnished with a copy of records or summaries, on request, with adequate verification. More detailed information on patient records is available from KMA and also published in the KMA *Journal* in the January 1991 issue. Members are urged to comply with these guidelines.

As a general comment, the Council again notes that many complaints result from a lack of communication between physicians and patients. This lack of communication poses a detrimental influence to the physician-patient relationship and also obviates the dictates of appropriate risk management procedures. Again, members are urged to take the necessary time to communicate with patients in an open and compassionate manner.

The Council is honored to serve the Association, and urges that all members seek to focus on the humane and compassionate healing aspect of medicine for which we are all trained.

William P. VonderHaar, MD
Chair

Report of the Rural Kentucky Medical Scholarship Fund, Inc

The Rural Kentucky Medical Scholarship Fund, Inc, (RKMSF) attempts to meet the medical needs of the rural population by alleviating the maldistribution of physicians. RKMSF currently administers two worthwhile programs in its efforts to meet this goal.

The first program provides low interest loans to medical students. Any loan recipient who practices primary care medicine in a county in critical need of physicians will be forgiven one loan for each full year of practice in the approved county. Any recipient practicing in a designated rural county facing a primary care physician shortage which is less than critical must repay his/her loans at a discounted interest rate which is determined yearly (currently 3.00%). Interest accrues from the date of the loan until payment is due.

For the school term 1993–94, the RKMSF made scholarship loans to 5 new applicants in the amount of $10,000 each at 3.00% interest, and 21 loans to prior student recipients. A total of $260,000 was expanded in scholarship loans for 1993–94. In 1992–93, $260,000 was also expended.

Since its inception in 1946, the Rural Kentucky Medical Scholarship Fund has granted 565 loans. There are currently 47 medical students/residents who have received loans from the RKMSF. The loans are granted for an eight-year period. Five recipients are entering residency programs in 1993 — two in family practice, two in pediatrics, and one in internal medicine. Nine recipients are currently enrolled in residency programs, and three recipients are entering practice in 1993. The remaining 30 recipients are currently in medical school.

There were three recipients who received forgiveness for loans in 1992–93, and seven recipients completed their financial and/or practice obligations in 1992–93.

The second program administered by RKMSF is the Establish Practice Grant Program (EPGP). The EPGP provides money to practicing physicians to assist in paying prior educational loans. For each year a physician in the EPGP practices in a critical county, he/she will be granted $10,000 to be used toward an educational debt, with a maximum of $40,000 granted per physician.

Five physicians are currently participating in the EPGP and two physicians are on the "waiting list." Since its inception in 1989, one physician's participation in the EPGP has been completed. Upon completion of a year of practice, each physician receives a grant of $10,000 to help defray his/her educational debt. The physicians are practicing in the counties of Adair, Knott, Menifee, Spencer, and Knox.

The RKMSF has two main sources of income: interest accrued on the scholarship notes which are paid back or brought out and interest on investments. The average maturity of RKMSF investments is just under two and one-half years, with an average yield of 8.63%.

The Kentucky Medical Association continues to provide its support which greatly contributes to the success of the Fund. The RKMSF, while operated through the KMA, is a separate, nonprofit corporation, having its own Officers and Board of Directors. This report is furnished as an informational item.

Donald R. Stephens, MD
President

Report of the Physician-Attorney Liaison Committee

The Physician-Attorney Liaison Committee continues to address complaints between the two honored professions.

At its meeting on January 28, 1993, the Committee reviewed a formal complaint filed by an out-of-state attorney against a Kentucky physician for failure to produce patient records upon issuance of a subpoena. This matter was resolved by agreement of the parties, and no action by the Committee was necessary.

In other matters, the Interprofessional Code continues to be published periodically in the *KMA Journal* and the *KBA Bench and Bar.* Comments have been solicited from both professions as to how the Interprofessional Code may be updated and improved. The Committee is also obtaining the opinion of an antitrust attorney as to whether it can continue to review deposition fee complaints and issue to the parties opinion letters regarding the appropriateness of said fees.

The Committee also reviewed the Kentucky Supreme Court Advertising Rules. This review was prompted by a complaint received from a Kentucky physician concerning an attorney's newspaper advertisement regarding medical malpractice. It was the consensus of the Committee that is was powerless to prevent this advertisement or similar advertisements due to a recent United States Supreme Court decision.

The Committee continues to study ways to improve the relationship between physicians and attorneys. Joint seminars, joint articles, and formation of a speakers' bureau are several of the options being entertained by the Committee.

The Committee thanks the House of Delegates for the opportunity to serve and looks forward to fulfilling its objectives in the coming year.

Lynn L. Ogden, MD
Chair

Report of the Young Physicians Steering Committee

The Young Physicians Steering Committee held two meetings this year, with a third one scheduled prior to KMA's Annual Meeting. The purpose of our Committee is to discuss ways to identify and address issues of interest to young physicians and increase young physicians' involvement in organized medicine.

Our Committee works in conjunction with the AMA Young Physicians Section which was formed in 1987 to provide young physicians a direct voice in policy decision making in all levels of organized medicine. Kentucky sends a YPS Delegate to the Annual and Interim Meetings of the AMA House of Delegates. We have found it very helpful and enlightening to participate directly in establishing policies that will affect our careers.

A special young physicians' luncheon was held again last year. We were pleased to have Joy Maxey, MD, Atlanta, Chair-Elect of the AMA-YPS, as our speaker. We are planning to hold this luncheon again this year at noon on September 28 in the Keeneland Suite of the Hyatt Regency Louisville. Any young physician member of KMA is welcome to attend. The Committee would like to acknowledge, with appreciation, the generous sponsorship of the luncheon by the Kentucky Medical Insurance Company.

Our Committee continues to be interested in AMA efforts to repeal the inequitable Medicare payment cuts for "new physicians." Provisions to restore full payment were passed by both Houses of Congress, only to be vetoed by President Bush because they were a part of an aid-to-cities bill which was felt to be too costly. The AMA has arranged for the proposal to be reintroduced this year and is again making it a priority for passage.

This year, we will again use special ribbons to identify young physicians attending the KMA Annual Meeting. The AMA defines young physicians as being under the age of 40 or in the first five years of professional practice.

The Committee appreciates the continuing support of the KMA Board of Trustees and the officers of the Association.

Ford Threlkeld, MD
Chair

Report of the Medical Student Section

The KMA Medical Student Section has been involved in numerous activities at the local, state, and national levels this year. Although the KMA-MSS Governing Council did not meet again in 1992–93, efforts are underway to reactivate the Council and establish regular meetings between the two medical schools.

University of Kentucky — Recruitment was the number one goal last fall as the University of Kentucky Chapter welcomed the incoming class with a luncheon and presentation on the benefits of belonging to the KMA and AMA. These efforts were rewarded as 80% of the new class had joined by the end of the recruitment drive. Chapter President Mark Cannon received an Outreach Program Award at the 1992 AMA-MSS Interim Meeting at which he was also selected as an alternate member of an AMA-MSS Reference Committee.

"Community Awareness" was the service project that the UK Chapter pursued this year. The first of two lectures was held in December 1992 on "Domestic Violence and the Role of the Health Professional." Approximately 130 medical students, residents, and attendings heard speakers from the Lexington Domestic Violence Prevention Board. Because of the in-depth nature of this program and the efforts of the UK Chapter President, an AMA Policy Promotion Grant was awarded to the Chapter to fund the second lecture held in April on "Child Abuse: What Should I Look For?" Again, over 100 persons attended this program. The UK Chapter particularly thanks the AMA and KMA for its support in making the lecture series a success.

University of Louisville — Efforts to recruit student members for the UL Chapter began last summer with a letter-writing campaign and representation at Health Awareness Week. Approximately 50 students joined the AMA through the Outreach Program and UL Chapter President David Verst also was recognized at the AMA-MSS Interim Meeting for recruitment. Students from the University of Louisville represented the Section at both AMA-MSS meetings in December and June.

UL Senior Kela Lyons was the recipient of one of only two internships awarded in 1993 by the AMA Division of Government Affairs. She spent four weeks in Washington, DC, attending various committee hearings and working on specific issues with AMA lobbyists on Capitol Hill.

The KMA-MSS cosponsored the second joint statewide meeting with the KMA Resident Physicians Section September 15 in Louisville. Almost 60 residents and students attended the meeting and heard presentations on "Humor in Medicine" and "How to Avoid Getting Sued." We look forward to the 1993 session scheduled for September 28 on "Changing Dimensions of Medicine."

The Section would like to thank the officers, delegates, and all KMA members for their support of medical student activities and the opportunity given to us to have a voice and be involved in the affairs of organized medicine.

Mark Cannon, UK President
David Verst, UL President

Report of the Resident Physicians Section

The KMA Resident Physicians Section has been involved in numerous activities this year at both the state and national levels. Representatives from the residency programs at the University of Louisville, University of Kentucky, Trover Clinic, and St. Elizabeth's form the Section's Governing Council which meets regularly to discuss matters of concern to residents in Kentucky and in the nation.

The Council met four times this year, with the first meeting held during the 1992 KMA Annual Meeting. Discussion of health care reform issues and RPS Resolutions was the focus of this meeting. The Council continues to be successful in effecting policy at the state level and, since 1984, has had Resolutions adopted at every session of the KMA House of Delegates.

The two RPS Resolutions adopted by the 1992 House called for KMA to oppose legislative proposals that institute an involuntary service requirement for physicians trained in Kentucky and to request the Kentucky Cabinet for Human Resources to survey out-of-state physicians trained in Kentucky on reasons why they decided to leave the state. The Resolutions were referred to the Committee on State Legislative Activities and Physician Manpower Committee for implementation and are considered in those reports.

The KMA-RPS and Medical Student Section held its second annual joint session on September 15 with approximately 60 residents and students in attendance. Clifford Kuhn, MD, Louisville, provided a relief to the pressures of medical training with his presentation on "Humor in Medicine." On a more serious side, Randolph Starks, Manager, Claims Prevention, Kentucky Medical Insurance Company, spoke on "How to Avoid Getting Sued." Officers from KMA and the AMA-RPS also reported on state and national legislative activities.

New officers were elected at the February 17 meeting and the three Council members who attended the AMA-RPS Interim Meeting in December reported on actions taken by the AMA-RPS House. Several residents who serve on one or more KMA committees summarized some of the current activities in which their committees are involved.

The Council met again on April 21 to finalize plans for the 1993 RPS and MSS Annual Meeting to be held September 28 in Louisville. A panel discussion on "Changing Dimensions of Medicine" will deal with managed competition, the legislative arena, choosing primary care vs. a specialty, and financing a medical career. Panelists for this program are Robert R. Goodin, MD, AMA Delegate from Kentucky; Don Chasteen, KMA Director of Public Affairs; H. David Wilson, MD, Associate Dean for Academic Affairs, UKMC; and William Scott Black, MD, a practicing family physician in Barbourville.

For the first time ever, the KMA-RPS filled its allotted number of seats at the AMA-RPS Annual Meeting and we would like to acknowledge and expresses appreciation to the KMA and the residency directors at St. Elizabeth's, Trover Clinic, and the University of Louisville for their support for this meeting. Five residents represented the KMA Section at the meeting held in Chicago on June 11-13. Our Delegate to the AMA-RPS, Todd Prewitt, MD, led the delegation which included Drs Baretta Casey, David Butler, Pradip Patel, and Judy Linger.

We are pleased to report that two KMA residents gained national offices at the June meeting. Dr Linger, a current member of the AMA-RPS Governing Council, was elected to the AMA-RPS Alternate Delegate to the AMA House

and Dr Casey was appointed by the AMA Board of Trustees to serve on its Women in Medicine Advisory Panel.

Because of our increased activity at the national level, we are pleased to announce that the AMA plans to sponsor a special meeting exclusively for Kentucky residents in the late fall and the Council, at its meeting on July 28, discussed possible topics and speakers for this session. In addition, the Council heard reports on actions taken during the AMA-RPS Annual Meeting and worked on Resolutions for submission to the 1993 KMA House of Delegates.

Two issues of the KMA-RPS newsletter, "KY Residents Report," were sent to all Kentucky residents this year outlining activities of the Section and encouraging participation of more residents in organized medicine. Currently, In-Training membership in KMA is a little more than one-fourth of all residents. Since we are the physicians who will be starting new practices over the next five years, we are concerned that more residents don't realize that what happens in Frankfort and Washington today will affect all of us tomorrow. We are grateful to those programs and departments that encourage participation by their residents in organized medicine and urge all others to do so.

As President, I want to thank the individual members of the Governing Council for their hard work this year. We have had excellent participation at all the Council meetings from each of the four residency programs and I appreciate the dedication and time given to participate. On behalf of the Council, I wish to also thank the KMA Officers, Board of Trustees, and House of Delegates for their continued support and for giving residents the opportunity to have direct input in issues affecting the future of our profession.

Baretta R. Casey, MD
President

Report of the Ephraim McDowell Cambus-Kenneth Foundation, Inc.

The Ephraim McDowell Cambus-Kenneth Foundation, was incorporated on May 26, 1988, as a not-for-profit Kentucky corporation and exists exclusively for "charitable and educational purposes in promoting an appreciation of history through the acquisition, restoration, and preservation of buildings and properties having special historic significance."

The Foundation was formed by the Kentucky Medical Association for the purpose of accepting from Mr Joe A. Wallace and Mrs Cecil Dulin Wallace, upon their deaths, the 550-acre Cambus-Kenneth Farm located in Danville. This Farm was owned at one time by the pioneer physician, Ephraim McDowell, MD; served as his summer home; and was the site of his death. Additionally, the assets of the former McDowell Memorial Fund, including the McDowell House and Apothecary Shop, also located in Danville, were conveyed to the Foundation by the Kentucky Medical Association.

The Foundation's Board of Directors met on September 17, 1992, and elected the following corporate officers for 1992-93: William B. Monnig, MD, President; G. Russell Shearer, MD, Vice President; and William P. VonderHaar, MD, Secretary-Treasurer.

The McDowell House Managers Committee operates under the auspices of the Foundation to supervise the maintenance and operation of the McDowell House and Aopthecary Shop. A report on the financial status of the McDowell House will be presented to the Foundation's Board of Directors at its annual meeting in September. However, finances seem to be in good order. The Managers Committee is placing additional emphasis on the "Friends of the McDowell House" project in an attempt to increase the number of Friends and to increase donations. The Managers Committee continues to meet on a quarterly basis, and two members are elected to serve with the chairman as members of the Ephraim McDowell Cambus-Kenneth Foundation Board of Directors.

The Kentucky Medical Association Alliance has continued to play an important role in maintaining and adding to the collection of the McDowell House and has been very faithful in its participation.

On a sad note, Joe A. Wallace passed away in December 1992. The Foundation's sympathies go out to Mrs. Wallace. Memorial gifts to the Foundation in honor of Mr Wallace totaled $2,160. These gifts can be used only for the benefit of the Foundation. The Foundation's Planning Committee met with Mrs Wallace in February 1993. Mrs Wallace announced that she deposited $18,000 from the sale of antiques into a Foundation account to be utilized under the direction of the Foundation's Board of Directors. Mrs Wallace also proposed that the Foundation explore the possibility of hiring a full-time director to oversee the operation of the Farm and the McDowell House. The Planning Committee continues to study Mrs Wallace's request.

The Foundation Board would like to thank Russell Shearer, MD, Chairman of the McDowell House Managers Committee, as well as the Committee members, McDowell House staff, and volunteers who have made the operation of the Foundation a resounding success during the last year. I would like to express my personal appreciation to the other members of the Foundation Board for their service this year.

William B. Monnig, MD
Chair

END OF CONSENT CALENDAR ITEMS

Report of the Membership Committee

The Membership Committee is pleased to report that 1992 was a banner year for Association membership. Not only did KMA have its highest increase ever in Active members — a net gain of 203 — but it also enjoyed the largest percentage net increase in any year of 5.4%. These gains are particularly significant when the average increase over the last 22 years has been 60 and the average percentage increase has been 2%. In addition, 334 new Active members were recruited in 1992, 45% more than in 1991. With 107 new In-Training members and 17 new Associates, a total of 458 new members were added to the Association.

Although membership gains have not been quite as dramatic in 1993, we are pleased to report that, for the first time, Active members number in excess of 4,000 and we are experiencing a 3.2% growth this year.

We recognize that the intensity of the health care reform debate has been a significant factor in membership growth as more and more physicians see the importance of a unified voice for medicine. In addition, many of the recruitment programs during the last decade with medical students and residents are coming to fruition as young physicians continue their support of organized medicine when they establish practice.

This fact is borne out when comparing data from the 1983 Membership Committee report that 63% of all nonmembers were age 40 and under and only 46% of the physicians in this age group were KMA members. The 1993 Demographic Study of Membership notes that 35% of all nonmembers are in the 40 and under age category. Sixty percent of Kentucky's young physicians are members of KMA.

The Membership Committee met on February 17, 1993, to review data from the 1993 Demographic Study of Membership and to make recommendations for activities to enhance the recruitment and retention of physicians, residents, and medical students in organized medicine. We point out several key observations from the Study which reconfirm our position that membership development must be ongoing and that we must strive through every means possible to retain current members and convince nonmembers to join:

- A high percentage of physicians have dropped their membership — 35% of all nonmembers. In several Trustee Districts more than half of all nonmembers were former KMA members.
- More than half of all nonmembers are in a primary care specialty and a little more than one-fifth are international medical graduates.
- Gains in membership were noted among women physicians in 1992; yet one-fifth of all nonmembers are women and in several Districts that number ranges from 26% to 32%.
- Ten of the 15 Trustee Districts have a lower percentage of membership in 1992 compared to 1988 and eight Districts have membership levels below 75%.

The Membership Committee forwarded the complete Demographic Study to each KMA Trustee and Alternate Trustee asking them to increase their efforts to involve more physicians in organized medicine and to set a goal of at least 75% membership in their Districts. A letter-writing campaign was undertaken by several Alternate Trustees and the Committee would like to thank Doctors Larry Wilson (5th District), John Ammon (8th District), and Robert McKenney (9th District) for their efforts.

Recruitment for 1993 membership began in August 1992 with the first of 8 statewide mailings and an additional 15 targeted mailings. In addition, routine contacts are made on an almost daily basis to physicians new to the state or just starting practice. To date, we have gained 143 new members from these efforts alone.

The KMA membership videotape, which has been a successful recruitment tool since its development in 1988, was used in January in a targeted mailing to nonmembers licensed during the past two years. A 20% response to this mailing, and an overall response of 14% to the 1,000 tapes mailed since 1988, reemphasizes the usefulness of this vehicle to reach nonmembers and the Committee hopes to be able to develop a new recruitment video in the future.

In addition to the videotape campaign, other recruitment efforts were directed at specific segments of the nonmember population. KMA participated in the AMA "Women in Medicine" Month and a number of women leaders were featured in the September 1992 issue of *The Journal of the Kentucky Medical Association*. The Committee would like to thank Drs Ardis Hoven, Beverly Gaines, Mary Ann Barnes, and Baretta Casey for their contributions to the "Focus on Women in Medicine" article. Reprints of this feature were used in two separate recruitment mailings and resulted in 14 additions. Overall, 65% of women physicians belong to KMA, a small increase from 62% last year. This is less, however, than the 78% membership of all practicing physicians.

At its February 17 meeting, Committee members also reviewed ways to involve more young physicians, including better marketing of the current graduated dues structure for physicians in their first and second years of practice and the possibility of creating mentor groups within the medical school structure. Although the ideal situation would be to have dialogue sessions between students and residents and then between residents and practicing physicians, with the extensive curriculum changes currently underway at both medical schools due to health care reform, it was felt that this would be a particularly difficult time to initiate a mentor program. Further discussion would take place on this issue as the Committee works with the two county medical societies in coordinating such projects.

Retention, a vital part of the overall membership plan, received additional emphasis this year. Following the initial billing in mid-October, five separate mailings were sent to encourage continued membership. Trustees and county society secretaries were also asked to personally contact members who had not renewed. We are concerned at the number of Active members who left the state last year (82, compared to 60 the previous year) and the number of Active nonrenewals (106, compared to 89 in 1992).

We continue to be successful in the "Superbill" program and have 100% KMA membership at four participating Kentucky clinics. We appreciate the clinic administration at Trover, Morgan-Haugh, Cave Run, and Daniel Boone Clinics for their help in implementing this efficient manner of dues processing and for their support of organized medicine.

The Committee is committed to the development of membership among students and residents. KMA Medical Student Section Presidents at both the University of Louisville and University of Kentucky were recognized for their recruitment efforts at the AMA Interim Meeting in December, netting 127 new student members (49 at UL, 78 at UK). Currently, 66% of the UL students and 85% of the UK students are members.

A total of 50 new residents were recruited at House Staff Orientations held at the University of Kentucky on June 25 and the University of Louisville on June 30. The Committee is grateful to Andrew Pulito, MD, and William VonderHaar, MD, for representing the Association at this year's Orientations.

The Membership Committee sponsored 11 practice management workshops (17 individual sessions) during 1992-93, with a total attendance of 542 physicians, spouses, and office personnel. Seminars held this year dealt with starting a practice, Medicare, retirement, CPT coding, collections, marketing, and managed care. We welcome suggestions from KMA members on other seminar topics or services which will benefit the membership.

As has been our custom in this annual report, the membership status as of June 30, 1993, follows:

Membership Category	# as of 6/30/93	# as of 12/31/92
Active	3,996*	3,946
In-Training	269	297
Total Dues-Paying	4,517	4,479
Total KMA All Categories	5,733	5,887

(*As noted earlier in the report, additions since June 30 have already increased this number to more than 4,000.)

Recruitment for 1994 is now underway with promotion of a statewide "Member-Get-A-Member" outreach program. This peer-to-peer recruitment effort is open to all KMA members and will provide a dues discount incentive to recruiters based on the number of new members recruited. Participation forms and other program details have been published in the *Journal* and "Communicator" and the Committee encourages every Delegate and member attending the 1993 Annual Meeting to sign up for this program at the Membership Booth.

On behalf of the Membership Committee, we wish to thank all the physicians who have participated in personal recruitment this year and urge every KMA member to get involved in strengthening membership. You are the key to recruitment in your area as you talk with new physicians, hospital staff colleagues, or alumni from your medical school. Greater member support will make medicine's voice a more viable instrument in dealing with the challenges that lie ahead.

Harold D. Haller, Sr, MD
Chair

Recommendations, Reference Committee 6:
Reference Committee No. 6 reviewed the Report of the Membership Committee and would like to thank Chairman Harold Haller, MD, for his work and testimony to the Committee. It should be noted that KMA active membership has now surpassed 4,000 members for the first time in its history.

Reference Committee No. 6 recommends that the Report of the Membership Committee be filed.

RESOLUTION H

Publicity Campaign
Boyle County Medical Society

WHEREAS, the members of the medical profession and the Kentucky Medical Association, over the last two decades, have been the subject of much discussion and negative publicity; and

WHEREAS, the physicians of the Commonwealth of Kentucky need to develop a positive image and communications with the general public; and

WHEREAS, the Kentucky Medical Association is the largest voice of organized medicine and the physicians of this Commonwealth of Kentucky; now, therefore, be it

RESOLVED, that the Kentucky Medical Association develop and initiate a permanent and ongoing publicity campaign to bring to the attention of the people of the Commonwealth of Kentucky the *positive aspects* of the physicians of the Commonwealth of Kentucky; and be it further

RESOLVED, that this publicity campaign should be organized and ongoing on a permanent status until that time that the House of Delegates feels that the campaign is no longer needed; and be it further

RESOLVED, that the publicity campaign be reviewed by the Board of Trustees of the KMA on a quarterly basis.

FISCAL NOTE: To fund the ongoing positive publicity campaign of Kentucky physicians, $20 of the membership fee, or an assessment of $20, should be placed in a separate account to raise $120,000 toward this project.

Recommendations, Reference Committee 6:
Reference Committee No. 6 considered Resolution H, Publicity Campaign, submitted by the Boyle County Medical Society. The Committee heard testimony by members of the Boyle County Medical Society, the KMA Board of Trustees, and a number of KMA members, who expressed their support for and concern regarding this Resolution.

Reference Committee No. 6 recommends that the three "Resolveds" be deleted and that the following "Resolved" be substituted in their place:

"RESOLVED, that the Kentucky Medical Association appoint a public relations committee."

Reference Committee No. 6 recommends the adoption of Resolution H, as amended by deletion and substitution.

G. Irene Minor, MD, Delegate from Madison County, was recognized, who made a motion that Resolution H as originally proposed be adopted in lieu of the Reference Committee's recommendation. The motion was seconded from the floor, and a lengthy discussion enused.

Russell L. Travis, MD, Board Chair, stated that the Board of Trustees had noted that if Resolution H were to be adopted, a $30 dues increase, rather than $20, would be required to achieve the $120,000 in income addressed in the Resolution.

Dr Travis made a motion, on behalf of the Board, that a final Resolved be added to Resolution H to read: "Resolved, that the KMA Bylaws be amended to fund such a public education campaign by increasing Active Member annual dues from $400 to $430." The motion was seconded and carried.

A subsequent motion that a one-time assessment of $200 be levied, in lieu of a $30 dues increase, was defeated.

James F. Beattie, MD, Delegate from Warren County, proposed editorial changes to Resolution H, and made a motion that the words "publicity" in the first and second Resolveds be changed to "public education," and the word "publicity" in the third Resolved be changed to "educational." The motion was seconded from the floor and carried. The Vice Speaker then called for a vote to adopt Resolution H as amended from the floor. The motion carried.

Resolution H, adopted as amended by the House, reads as follows:

WHEREAS, the members of the medical profession and the Kentucky Medical Association, over the last two decades, have been the subject of much discussion and negative publicity; and

WHEREAS, the physicians of the Commonwealth of Kentucky need to develop a positive image and communications with the general public; and

WHEREAS, the Kentucky Medical Association is the largest voice of organized medicine and the physicians of this Commonwealth of Kentucky; now, therefore, be it

RESOLVED, that the Kentucky Medical Association develop and initiate a permanent and ongoing public education campaign to bring to the attention of the people of the Commonwealth of Kentucky the *positive aspects* of the physicians of the Commonwealth of Kentucky; and be it further

RESOLVED, that this public education campaign should be organized and ongoing on a permanent status until that time that the House of Delegates feels that the campaign is no longer needed; and be it further

RESOLVED, that the educational campaign be reviewed by the Board of Trustees of the KMA on a quarterly basis; and be it further

RESOLVED, that the KMA Bylaws be amended to fund such a public education campaign by increasing Active Member annual dues from $400 to $430.

Mr Speaker, Reference Committee No. 6 recommends the adoption of the report of Reference Committee No. 6 as a whole, as amended.

Mr Speaker, I would like to thank the members of the Reference Committee for their help in dealing with some very worthy, but controversial, issues in formulating this report. Other members of the Committee are: Robin M. Floyd, MD, Louisville; Vaughn M. Payne, MD, Louisville; Susan H. Prasher, MD, Ashland; and William C. Thornbury, Jr, Louisville. I would also like to thank Diane Maxey for her help in preparing this report.

Respectfully submitted,
REFERENCE COMMITTEE NO. 6
John D. Noonan, MD, Paducah, Chairperson
Robin M. Floyd, MD, Louisville
Vaughn W. Payne, MD, Louisville
Susan H. Prasher, MD, Ashland
William C. Thornbury, Jr, Louisville

Report of the Rules Committee of the House of Delegates

The Rules Committee was established by the House of Delegates to advise the Speakers on the conduct of operations of the House and to make recommendations on rules for standing operating procedures not addressed in the *Rules of Order* or the Constitution and Bylaws.

The Rules Committee met this year and considered a number of issues. Some related to scheduling various events throughout the Annual Meeting to help attendance and enhance attraction. These issues were presented to the Board of Trustees for consideration in developing future meetings.

Specific matters were discussed that relate directly to the functioning of House operations. In order to spread the volume of business commensurately among the Reference Committees, it was felt that the number of committees should be reduced from six to five. At the same time, it was felt that attention should be focused on new and young physicians in an effort to interest them in becoming involved in the organizational activities. For this reason, it was felt that the number of members on each Reference Committee should be raised from five to six, with emphasis on students, residents, and young physicians.

Based on situations Reference Committees have encountered in the past few years, it was noted that sometimes Resolutions are submitted which are not clear in intent. If the author of the Resolution or a representative of the idea being addressed is not present, the Reference Committee very often is not able to adequately deal with the issue. For this reason, it was felt that Reference Committees should be empowered to refer such Resolutions back to the author for clarification, and not process these Resolutions for business any further.

The Rules Committee respectfully stands ready to assist further, as needed.

Larry J. Wilson, MD
Chair

RECOMMENDATIONS:

1. The Rules Committee recommends that the number of Reference Committees be decreased from six to five.
2. The Rules Committee recommends the number of members on each Reference Committee be increased from five to six, with emphasis on students, residents, and young physicians.
3. The Rules Committee recommends that Reference Committees be empowered to refer Resolutions back to the author, without further processing, when the intent of the Resolution is not clear and the author or a representative of the concept being addressed is not present to provide clarification.

The Report of the Rules Committee was adopted by the House of Delegates.

Election of Officers

Joseph G. Weigel, MD, Somerset, Chair of the Nominating Committee, presented the slate of nominees for offices as follows:

President-Elect	Robert R. Goodin, MD Louisville

Dr Goodin was elected by acclamation, and escorted to the podium by Past Presidents Bob M. DeWeese, MD, and Wally O. Montgomery, MD.

Dr Weigel then presented the remainder of the slate of nominees. **An asterick (*) denotes the individuals selected for the positions indicated, following a written ballot.**

Vice President	Donald R. Neel, MD Owensboro *William H. Mitchell, MD Richmond
Secretary-Treasurer	William P. VonderHaar, MD Louisville

Dr VonderHaar was elected by acclamation.

Dr Weigel then presented names of the nominees for the AMA Delegation (term — January 1, 1994 to December 31, 1995):

Delegates to the AMA (two slots)	*Donald C. Barton, MD Corbin Harold L. Bushey, MD Barbourville *Ardis D. Hoven, MD Lexington William B. Monnig, MD Edgewood
Alternate Delegates to the AMA (two slots)	J. Gregory Cooper, MD Cynthiana Donald J. Swikert, MD Florence

Drs Cooper and Swikert were elected by acclamation.

It was noted that Dr Hoven's election as a Delegate to the AMA would create a vacancy in the position she held as AMA Alternate Delegate. The following nominations were received from the floor to fill the unexpired term of AMA Alternate Delegate (January 1, 1994 to December 31, 1994):

Alternate Delegate to the AMA	Harold L. Bushey, MD Barbourville
	*Preston P. Nunnelley, MD Lexington

Dr Weigel then submitted the following nominations for the offices of Trustees and Alternate Trustees on behalf of the Trustee District nominating committees, and each was elected by acclamation:

5th District Trustee	Joseph E. Kutz, MD Louisville
5th District Alternate	Larry J. Wilson, MD Louisville
6th District Trustee	Timothy K. Hulsey, MD Bowling Green
6th District Alternate	J. Michael Pulliam, MD Franklin
8th District Trustee	Mark F. Pelstring, MD Covington
8th District Alternate	John D. Ammon, MD Florence
11th District Trustee	G. Irene Minor, MD Berea
11th District Alternate	Richard A. Stone, MD Richmond
15th District Trustee	Paul R. Smith, MD London
15th District Alternate	Roger A. Acosta, MD Barbourville
4th District Alternate (2-year term)	Jeffrey B. Richardson, MD Elizabethtown

Election of 1994 Nominating Committee

The following physicians were elected by the House of Delegates to serve as the 1994 KMA Nominating Committee:

James E. Redmon, MD, Louisville, Chair
Donald E. Brown, MD, Somerset
Ralph L. Cash, Jr, MD, Princeton
W. Lisle Dalton, MD, Lexington
Susan H. Prasher, MD, Ashland

Speaker Clark adjourned the 1993 Session of the KMA House of Delegates at 9:35 PM.

1993-94 KMA Committees

KENTUCKY PHYSICIANS CARE OPERATING
Russell L. Travis, MD, Lexington, Chair
Harry W. Carloss, MD, Paducah
Ray A. Cave, MD, Leitchfield
Preston P. Nunnelley, MD, Lexington
Nelson B. Rue, MD, Bowling Green

SCIENTIFIC PROGRAM
Sonia R. Teller, MD, Louisville, Chair
J. Greg Cooper, MD, Cynthiana
Robert R. Goodin, MD, Louisville
W. David Hager, MD, Lexington
Ardis D. Hoven, MD, Lexington
Daniel E. Kenady, MD, Lexington
Gary J. Wahl, MD, Owensboro
Kevin Breen, MD, Louisville (resident)
Elizabeth Miller, Lexington (student)

SCIENTIFIC EXHIBITS
Richard A. Kielar, MD, Lexington, Chair
James P. Moss, MD, Louisville
John W. Ratliff, MD, Lebanon
Sibu Saha, MD, Lexington

AWARDS
Nelson B. Rue, MD, Bowling Green, Chair
Richard F. Hench, MD, Lexington
Wally O. Montgomery, MD, Paducah
Preston P. Nunnelley, MD, Lexington
S. Randolph Scheen, MD, Louisville

CONTINUING MEDICAL EDUCATION
W. David Hager, MD, Lexington, Chair
James L. Borders, MD, Lexington
Michael E. Daugherty, MD, Lexington
Richard D. Floyd, IV, MD, Lexington
Robert R. Goodin, MD, Louisville
Diller B. Groff, MD, Louisville
Michael D. Hagen, MD, Lexington
Raymond V. Mecca, MD, Ashland
Joseph S. Sanfilippo, MD, Louisville
Samuel R. Scott, MD, Lexington
Thomas K. Slabaugh, MD, Lexington
Alfred L. Thompson, Jr, MD, Louisville
William P. VonderHaar, MD, Louisville
Jim Brown, MD, Louisville (resident)
Ex-Officio:
Larry Eul, Louisville, KHA Representative
Gerald Swim, University of Louisville

COUNCIL FOR CONTINUING MEDICAL EDUCATION
James L. Borders, MD, Lexington, Chair
Karen M. Erbeck, MD, Louisville
James R. Gould, MD, Paducah
W. David Hager, MD, Lexington
Walter I. Hume, Jr, MD, Louisville
Vaughn W. Payne, MD, Louisville
Joseph S. Sanfilippo, MD, Louisville
Samuel R. Scott, MD, Lexington
Paul J. Sides, MD, Lancaster
Sonia R. Teller, MD, Louisville
Larry J. Wilson, MD, Louisville
Mary Stephenson, MD, Louisville (resident)
Ex-Officio:
Gerald Swim, University of Louisville

CANCER
Clinton C. Cook, III, MD, Louisville, Chair
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Thomas G. Day, Jr, MD, Louisville
Gilbert H. Friedell, MD, Lexington
Susan Galandiuk, MD, Louisville
Allen E. Grimes, Jr, MD, Lexington
Harry R. Kennedy, Jr, MD, Somerset
Kristie Jones Paris, MD, Louisville
Carol S. Milburn, MD, Crestview Hills
John A. Patterson, MD, Irvine
Barbara F. Phillips, MD, Lexington
Steven H. Pursell, MD, Louisville
Gary C. Vitale, MD, Louisville
Eric Lentsch, MD, Louisville (resident)
Ex-Officio:
Martha Hinton, Paducah
Wayne B. Miller, Louisville, KY Division, American Cancer Society

PHYSICIAN MANPOWER
Robert R. Goodin, MD, Louisville, Chair
Richard E. Aud, MD, Louisville
John D. Gover, MD, Bowling Green
Donald R. Kmetz, MD, Louisville
Gorden T. McMurry, MD, Louisville
William H. Mitchell, MD, Richmond
Alfred L. Thompson, Jr, MD, Louisville
Emery A. Wilson, MD, Lexington
Baretta R. Casey, MD, Madisonville (resident)
Kitty Hines, Louisville (student)
Jerry Lawson, Lexington (student)
Rob Martin, Louisville (student)

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David L. Douglas, MD, Frankfort
William C. Durham, MD, Louisville
Stanley A. Gall, MD, Louisville
Larry P. Griffin, MD, Louisville
Terrell D. Mays, MD, Elizabethtown
Charles R. Oberst, MD, Louisville
John A. Petry, MD, Louisville
Clinton R. Potts, MD, Louisville
Walter M. Wolfe, Jr, MD, Louisville
Kela Lyons, Louisville (resident)

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Albert H. Joslin, MD, Owensboro (Key Contact for Senator Ford)
Charles C. Smith, Jr, MD, Louisville (Key Contact for Senator McConnell)
Wally O. Montgomery, MD, Paducah (Key Contact for Congressman Barlow)
Nelson B. Rue, MD, Bowling Green (Key Contact for Congressman Natcher)
Samuel D. Weakley, MD, Louisville (Key Contact for Congressman Mazzoli)
Lee C. Hess, MD, Florence; Paul S. J. Kappes, MD, Bellevue (Key Contacts for Congressman Bunning)
Stephen B. Kelley, MD, Somerset; Donald C. Barton, MD, Corbin (Key Contacts for Congressman Rogers)
Preston P. Nunnelley, MD, Lexington (Key Contact for Congressman Baesler)

STATE LEGISLATIVE ACTIVITIES
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William R. Bradford, MD, Louisville
James D. Crase, MD, Somerset
John E. Downing, MD, Bowling Green
Edmond A. Hooker, MD, Louisville
Robert C. Hughes, MD, Murray
Shawn Jones, MD, Paducah
Lucian Y. Moreman, MD, Elizabethtown
John D. Noonan, MD, Paducah
Preston P. Nunnelley, MD, Lexington
William N. Offutt, IV, MD, Lexington
H. Michael Oghia, MD, Russell Springs
C. Kenneth Peters, MD, Jeffersontown
Scott B. Scutchfield, MD, Danville
John D. Stewart, II, MD, Lexington
Samuel D. Weakley, MD, Louisville
Larry J. Wilson, MD, Louisville
Diana Moore, Lexington (Alliance)
Robin Mark Floyd, MD, Louisville (resident)
Mark Cannon, Lexington (student)

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William P. VonderHaar, MD, Louisville, Secretary-Treasurer
William B. Monnig, MD, Edgewood
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William H. Mitchell, MD, Richmond
Don R. Stephens, MD, Cynthiana
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Gordon L. Hyde, MD, Lexington
T. R. Miller, MD, Lexington
Mark F. Pelstring, MD, Covington
Nat H. Sandler, MD, Lexington
W. Ed Shuttleworth, MD, Greenville
Denise L. Winland, MD, Louisville
Glenn S. "Sky" With, MD, Lexington
Harper Wright, MD, Bowling Green
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Barbara Cox, RN, Louisville (Alliance)
Jeff Omer, Louisville (student)

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Peter Hasselbacher, MD, Louisville
Benjamin Kutnicki, MD, Warsaw
Larry T. McClure, MD, Ashland
James W. Mold, MD, Louisville
Manjula K. Pandit, MD, Louisville
Hugh R. Peterson, MD, Louisville
Samuel R. Scott, MD, Lexington
Paul R. Smith, MD, London
Steven H. Smoger, MD, Louisville
W. Ford Threlkeld, MD, Frankfort
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Kristi Wright, Louisville (student)

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Earl P. Oliver, MD, Scottsville
Richard A. Stone, MD, Richmond
Russell L. Travis, MD, Lexington

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Alan Bornstein, MD, Louisville

E. Dean Canan, MD, Louisville
William L. Dowden, MD, Lexington
John H. Doyle, MD, Louisville
Harold T. Faulconer, MD, Lexington
Larry D. Florman, MD, Louisville
J. Roger Goodwin, MD, Bowling Green
James S. Holtman, MD, Louisville
Anita R. Kotheimer, MD, Shelbyville
Forrest S. Kuhn, Jr, MD, Louisville
Dwight L. Lindsay, MD, Louisville
Laszlo Makk, MD, Louisville
Roy J. Meckler, MD, Louisville
John D. Noonan, MD, Paducah
Robert P. Schiavone, MD, Louisville
Edward L. Scofield, MD, Louisville
L. Jack Scott, MD, Bowling Green
Stephen Z. Smith, MD, Louisville
Raymond C. Snowden, MD, Hopkinsville
Thomas R. Watson, MD, Louisville

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N. Roger Jurich, MD, Prestonsburg
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Ira B. Potter, MD, Lackey
Jeffrey L. Rice, MD, Frankfort
Frank K. Sewell, Jr, MD, Henderson
Eugene H. Shively, MD, Campbellsville
Robert E. Smith, MD, Covington
Lowell L. Stokes, Jr, MD, Louisville
Clarita Valdez-Vicher, MD, McDowell

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Marjorie R. Fitzgerald, MD, Louisville, Chair
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Jerry N. Clanton, MD, Louisville
Robert B. Cloar, MD, Madisonville
Robert C. Hughes, MD, Murray
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William M. O'Bryan, MD, Owensboro
Porter L. Ramsey, IV, MD, Frankfort
Edwin L. Rogers, MD, Lexington
Donald J. Swikert, MD, Florence
John R. White, MD, Lexington
John J. Whitt, MD, Louisville
Richard A. Wright, MD, Louisville
Amy Haney, MD, Edgewood (resident)
Robert A. Goodin, Louisville (student)

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Doane Fischer, MD, Lexington
Beverly M. Gaines, MD, Louisville
Alan M. Gardner, MD, Lexington
Ronald J. Lubbe, MD, Covington
Patricia K. Nicol, MD, Frankfort
John L. Roberts, MD, Louisville
A. Davis Sprague, MD, Henderson
Chandra M. Varia, MD, Martin
Donald Wilson, MD, Maysville
Sylvia L. Cerel, MD, Lexington (resident)

TECHNICAL ADVISORY COMMITTEE ON PHYSICIAN SERVICES (TITLE XIX)
A. O'tayo Lalude, MD, Louisville, Chair
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Larry G. Crick, MD, Henderson
Richard A. Stone, MD, Richmond
David W. Suetholz, MD, Taylor Mill
Ex-Officio:
William T. Watkins, MD, Somerset

COMMUNITY AND RURAL HEALTH
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Timothy D. Costich, MD, Lexington
Meredith J. Evans, MD, Middlesboro
Reginald F. Finger, MD, Frankfort
Sofia M. Franco, MD, Louisville
Francis J. Halcomb, MD, Scottsville
Ardis D. Hoven, MD, Lexington
Rice C. Leach, MD, Frankfort
R. Wathen Medley, MD, Owensboro
Wayne W. Myers, MD, Hazard
James B. Noble, MD, Beattyville
H. Michael Oghia, MD, Russell Springs
Clarkson T. Palmer, MD, Frankfort
E. D. Roberts, MD, Pikeville
George C. Rodgers, MD, Louisville
Donald J. Swikert, MD, Florence
Mark Wallingford, MD, Maysville
Baretta R. Casey, MD, Madisonville (resident)
David W. French, MD, Madisonville (resident)
Angela Moore, Lexington (student)

SCHOOL HEALTH, PHYSICAL EDUCATION, AND MEDICAL ASPECTS OF SPORTS
R. Quin Bailey, MD, Danville, Chair
James M. Bowles, MD, Madisonville
Bobby J. Brooks, MD, Campbellsville
David N. Caborn, MD, Lexington
R. John Ellis, Jr, MD, Louisville
Ralph T. Fossett, MD, Morehead
Linda H. Gleis, MD, Louisville
Mary L. Ireland, MD, Lexington
W. Ben Kibler, MD, Lexington
Thomas M. Loeb, MD, Louisville
William McManus, MD, Owensboro
Dan M. Miller, MD, Murray
Michael J. Miller, MD, Crestview Hills
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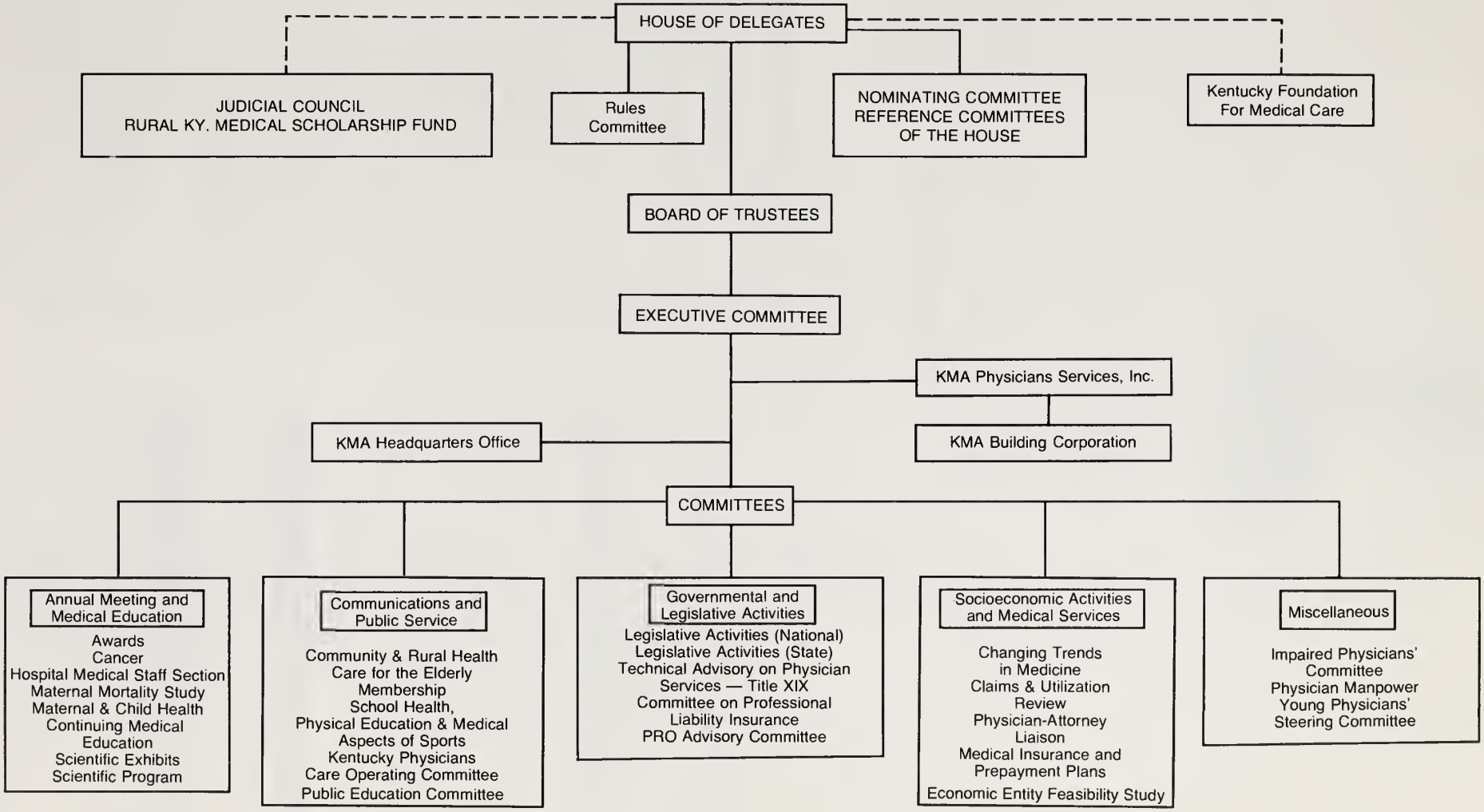
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Hypersensitivity to any component of this medication.

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WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acuta or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilapsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One tnal of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinoganasis, Mutaganasis, Impairmant of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimunum* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse expenences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitounnary				
Unnary Abnormality	2.4	2.9	0.7	1 2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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